Outcomes of the Polymer-based, Paclitaxel-eluting TAXUS Stent in Complex Lesions

Principal Results from the TAXUS-V Pivotal Randomized Trial

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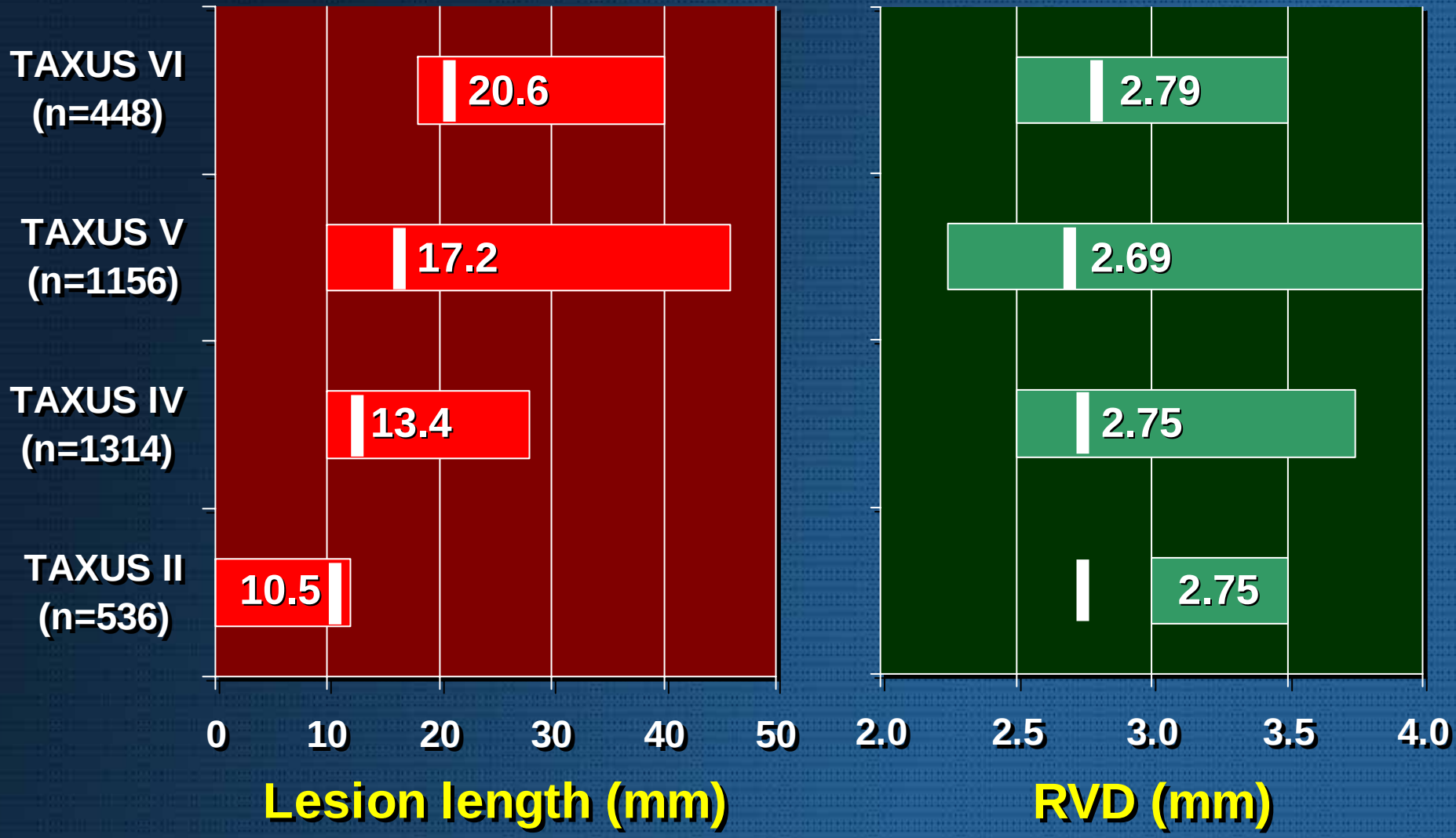
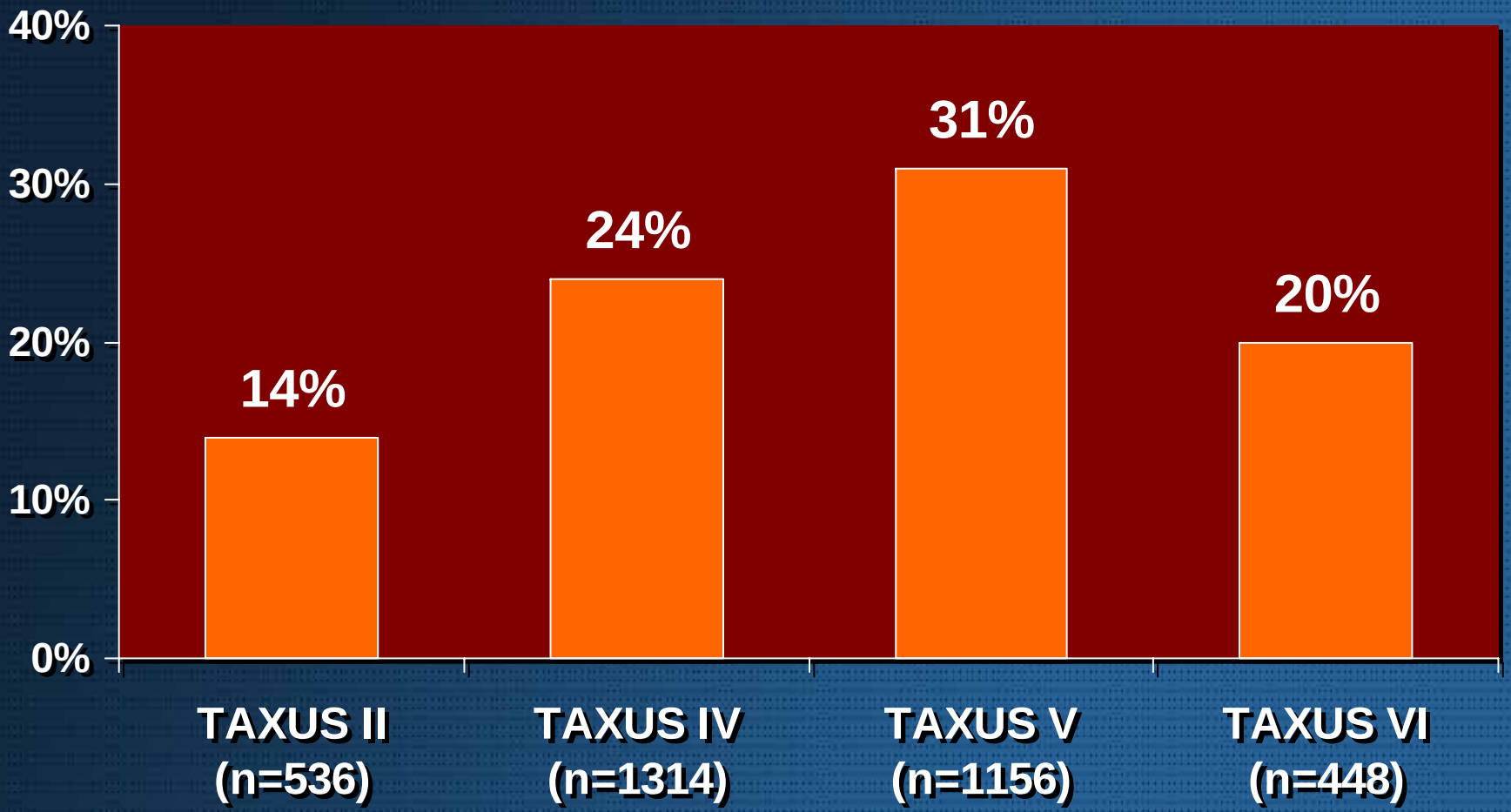
The Cardiovascular Research Foundation

TAXUS II, IV, V, VI: N=3,445



TAXUS II, IV, V, VI



Diabetes

Patient Flow

*No study stent attempted

Randomized (n=1172)

De-registered* (n=7)

De-registered* (n=9)

Intent-to-Treat (n=1156)

Control (n=579)

TAXUS (n=577)

9-month Clinical F/U (n=1127; 97.5%)

Control (n=567)

TAXUS (n=560)

9-month Angio F/U (n=990; 85.6%)

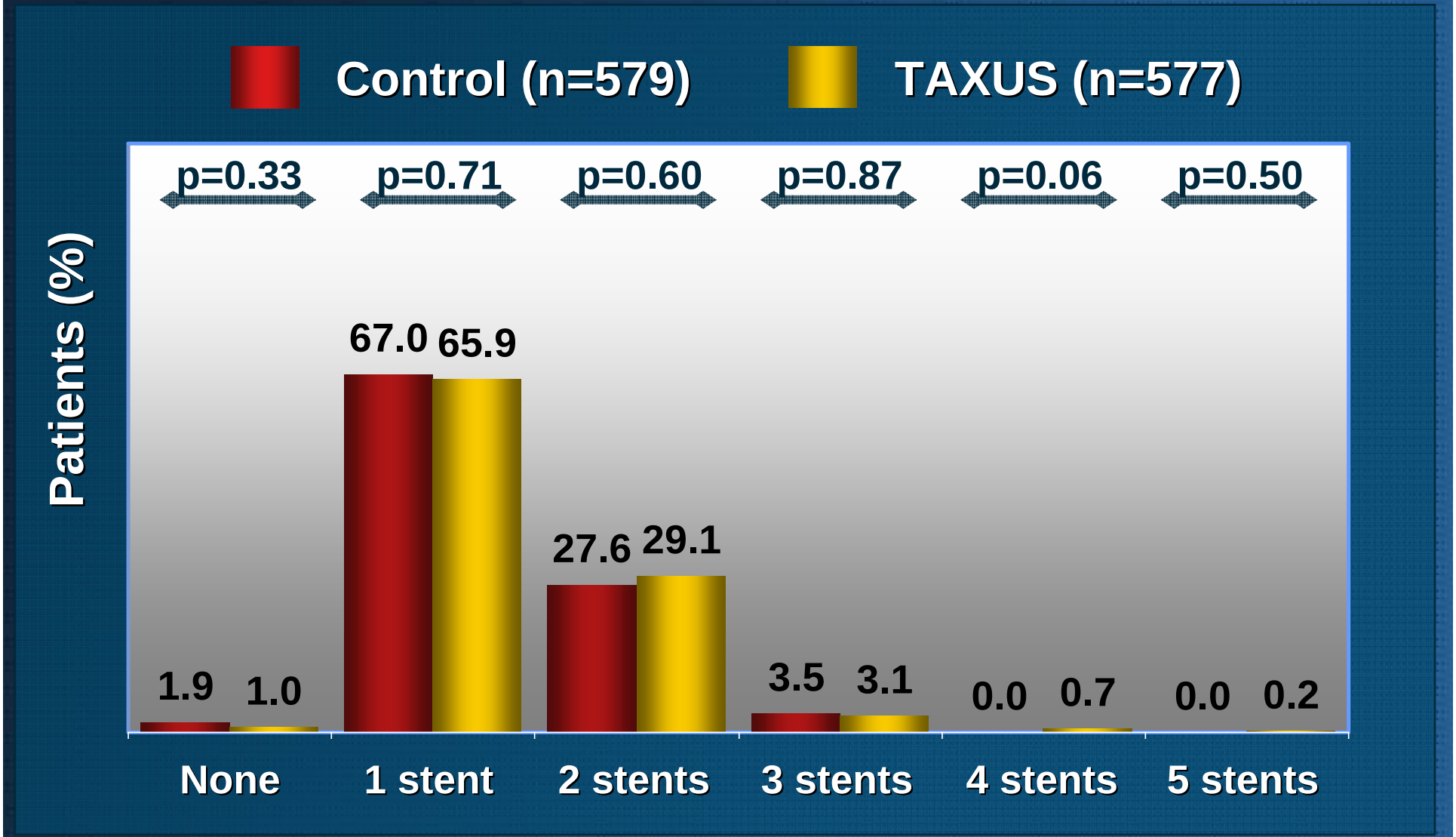
Control (n=492)

TAXUS (n=498)

Key Baseline Characteristics

	Control n=579	TAXUS n=577	P value
Age (yrs)	62.8 ± 10.8	62.9 ± 11.2	0.85
Male gender (%)	68.7	70.2	0.61
Diabetes mellitus (%)	29.9	31.7	0.52
- Insulin requiring (%)	9.2	8.5	0.76
Type B_2/C lesions (%)	79.9	75.4	0.68
Lesion Length (mm)	17.2 ± 9.4	17.3 ± 9.0	0.79
RVD (mm)	2.69 ± 0.56	2.68 ± 0.58	0.86
MLD (mm)	0.85 ± 0.39	0.86 ± 0.37	0.45
DS (%)	68.7 ± 12.2	67.9 ± 11.1	0.21

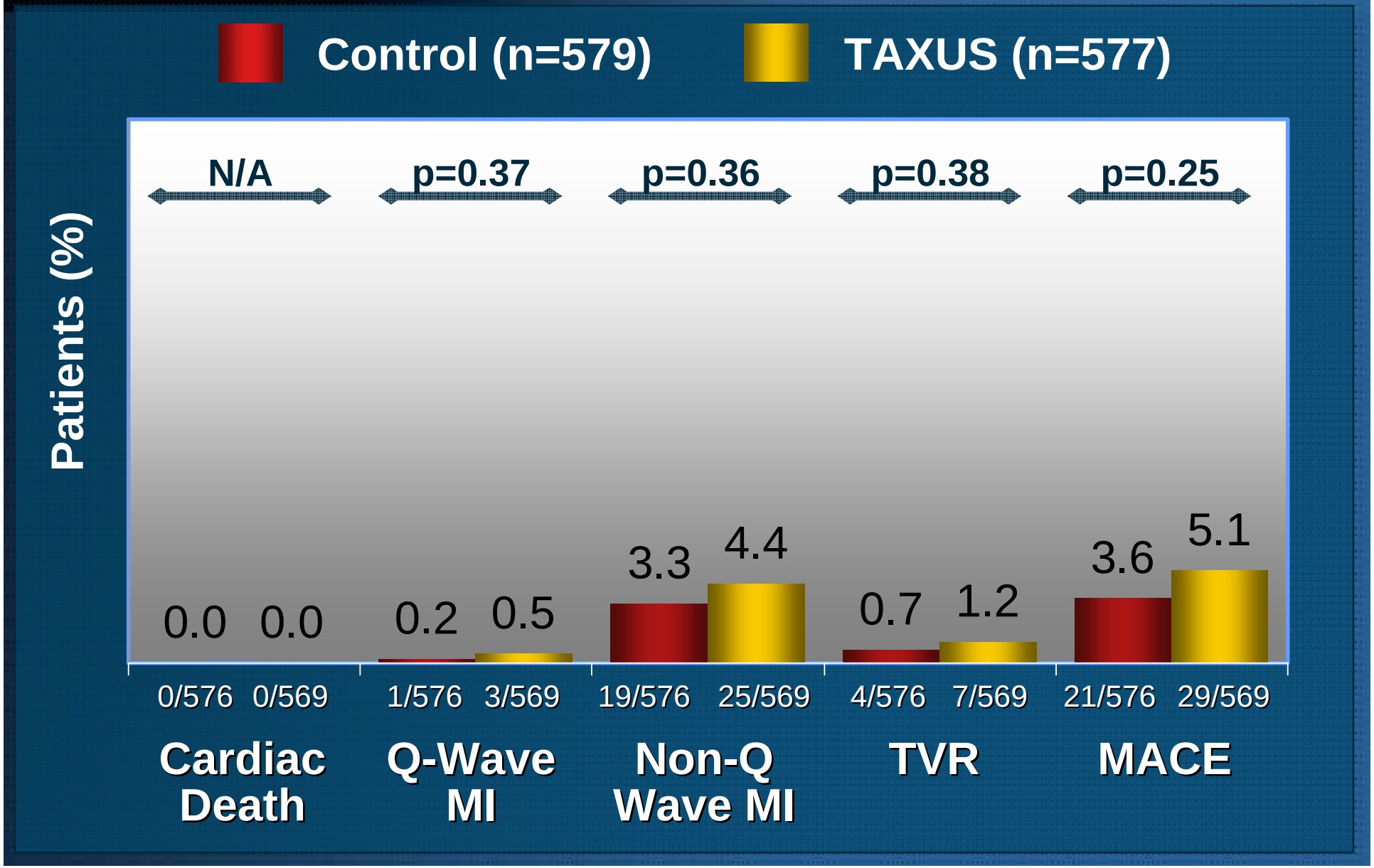
Number of Implanted Study Stents



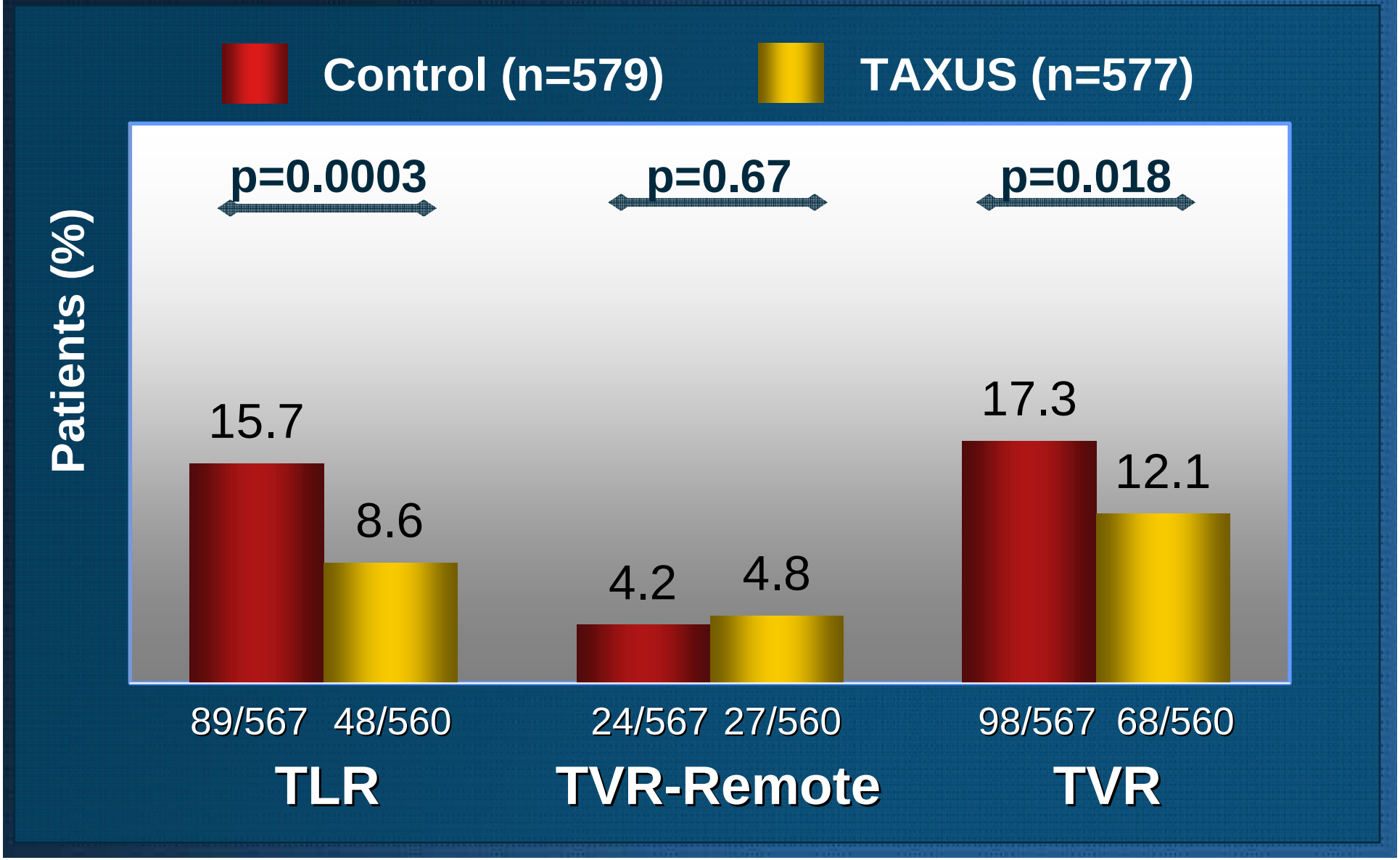
Procedural Characteristics

	Control n=579	TAXUS n=577	P value
Max. Infl. Pressure (atm)	15.5 ± 4.0	15.2 ± 3.9	0.37
Max. Balloon:Artery	1.10 ± 0.19	1.10 ± 0.20	0.73
Stent:Lesion Length	1.84 ± 0.83	1.82 ± 0.72	0.67
GP IIb/IIIa Inhibitors (%)	42.7	41.7	0.77
IVUS Used (%)	39.0	38.5	0.86
PCI Non Target Vessel (%)	20.0	19.4	0.82
Clin. Proc. Success (%)	96.0	95.3	0.57

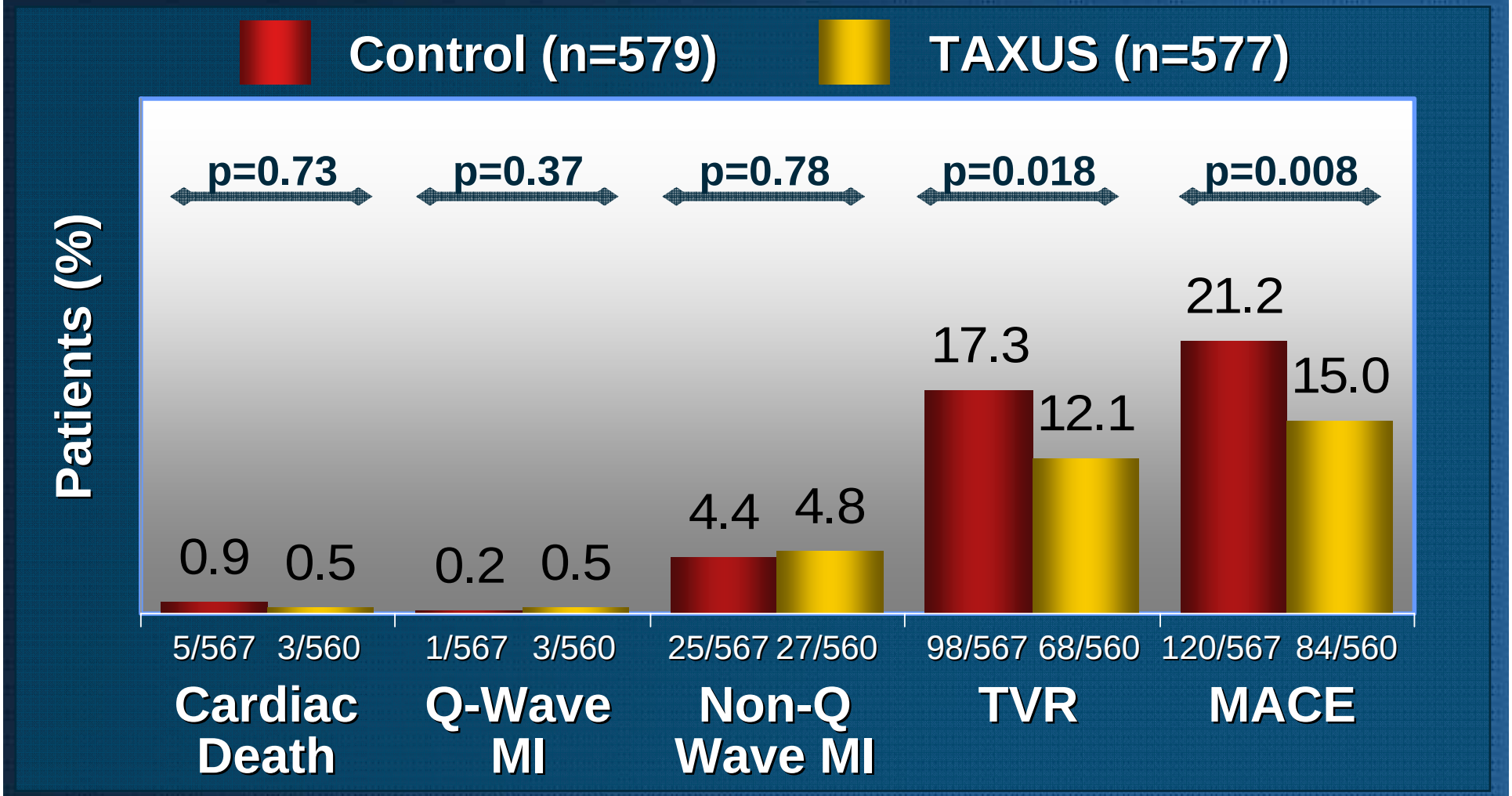
30-Day MACE


Control (n=579)
TAXUS (n=577)
Patients (%)
N/A
p=0.37
p=0.36
p=0.38
p=0.25
0.0
0.0
0.2
0.5
3.3
4.4
0.7
1.2
3.6
5.1
0/576
0/569
1/576
3/569
19/576
25/569
4/576
7/569
21/576
29/569
Cardiac Death
Q-Wave MI
Non-Q Wave MI
TVR
MACE

9-Month TVR and TLR

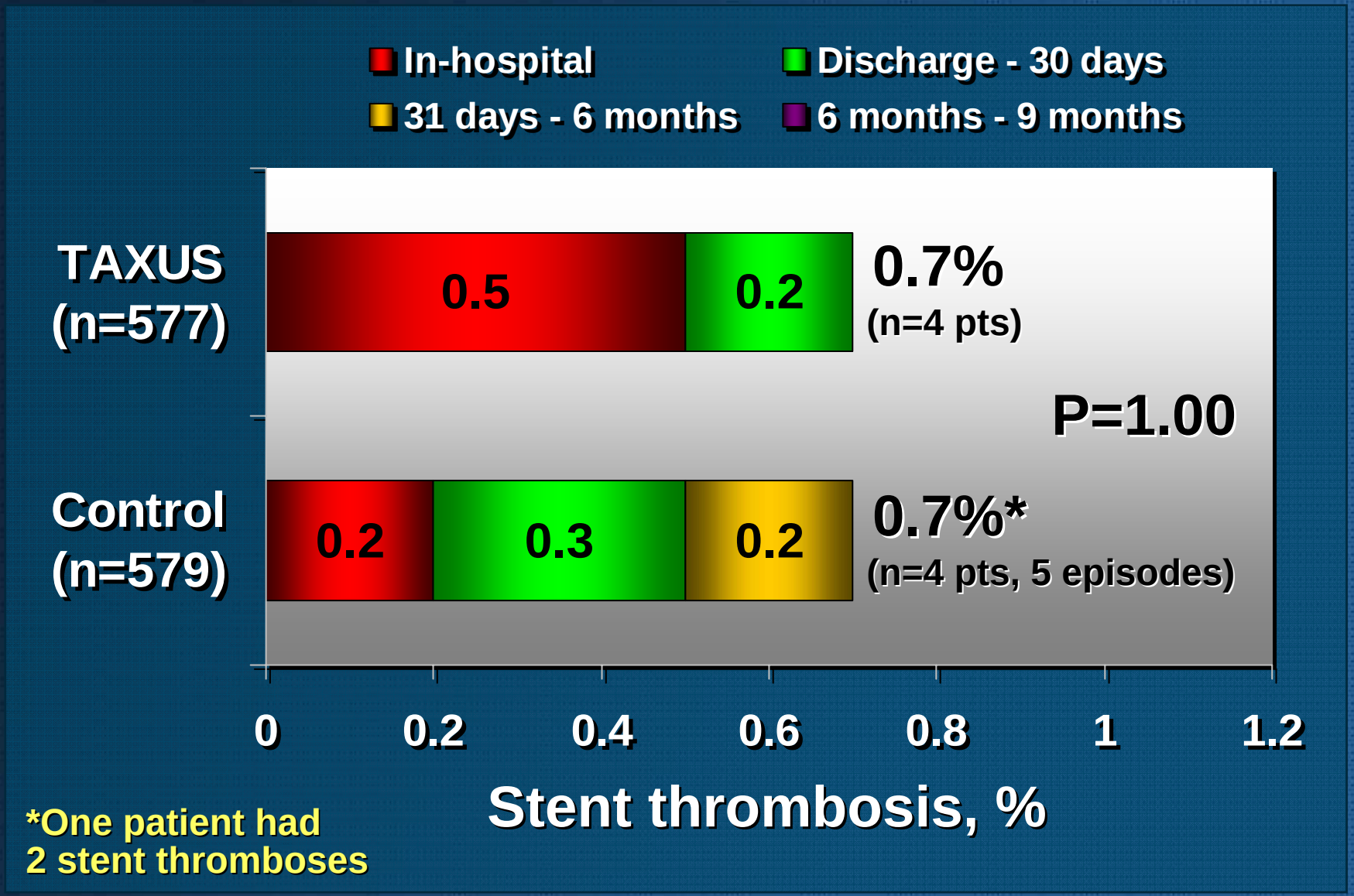


9-Month MACE



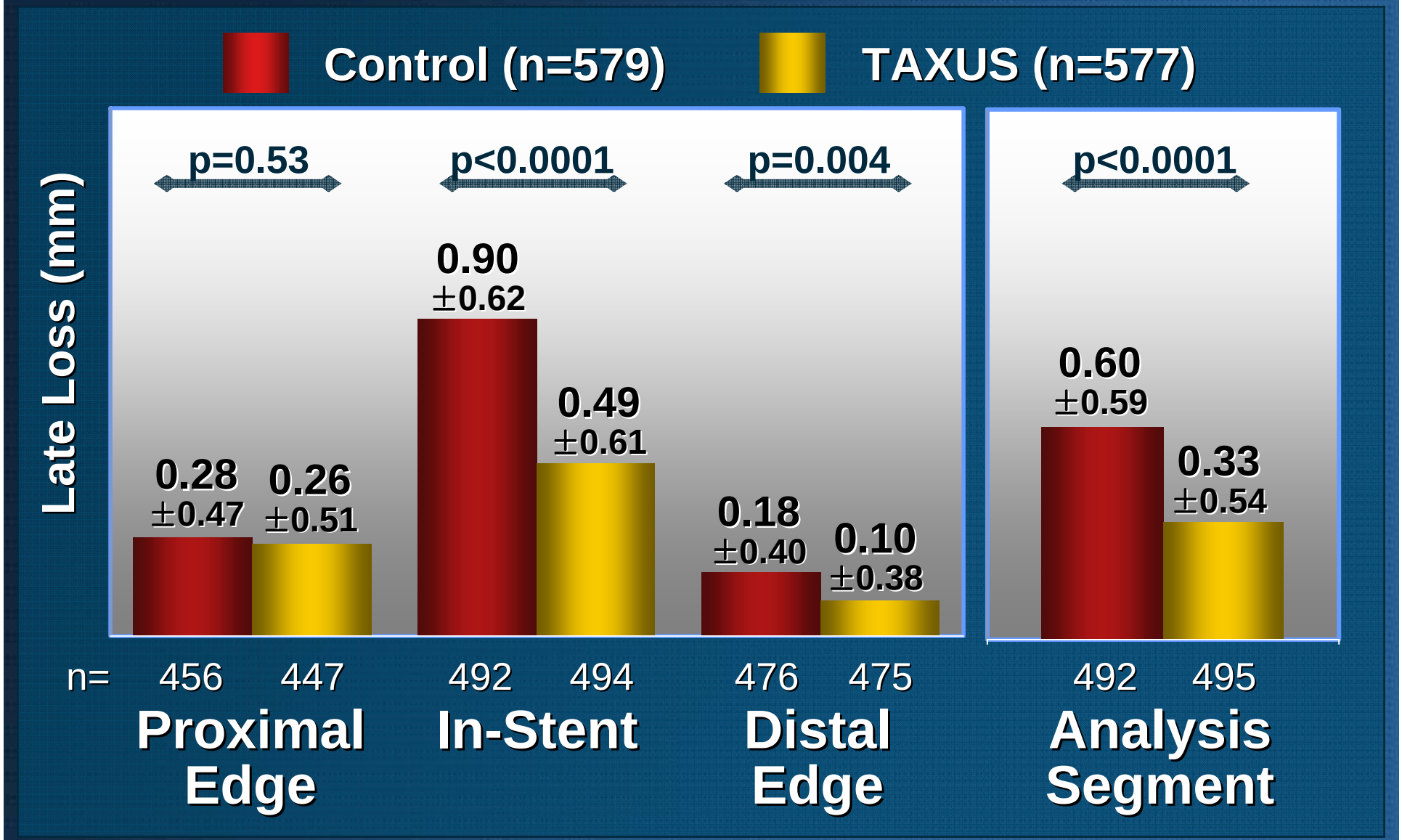
All Death: 1.4% (n=8) Control; 1.3% (n=7) TAXUS

Stent Thrombosis

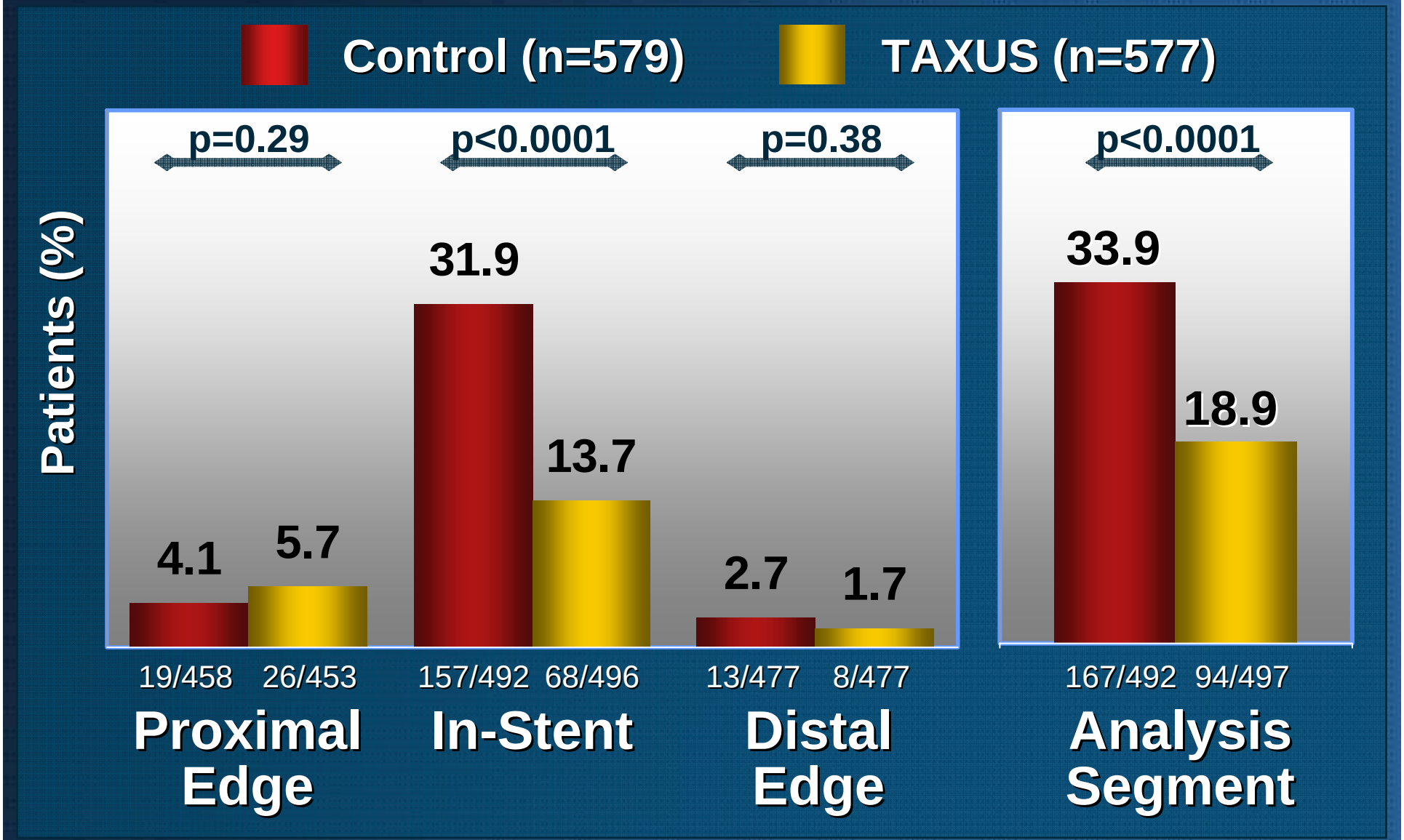


*One patient had 2 stent thromboses

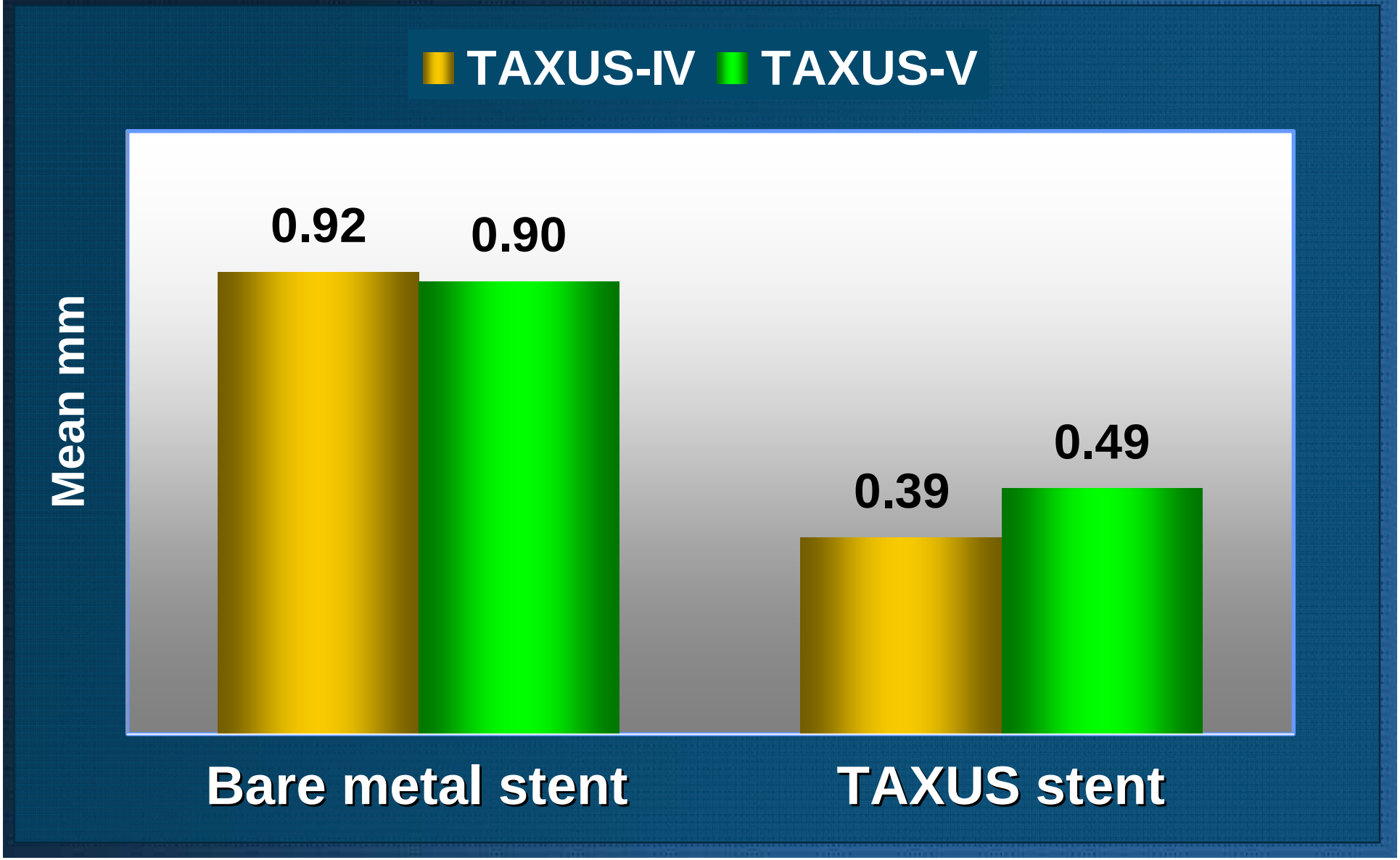
Late Loss at 9 Months (Paired)



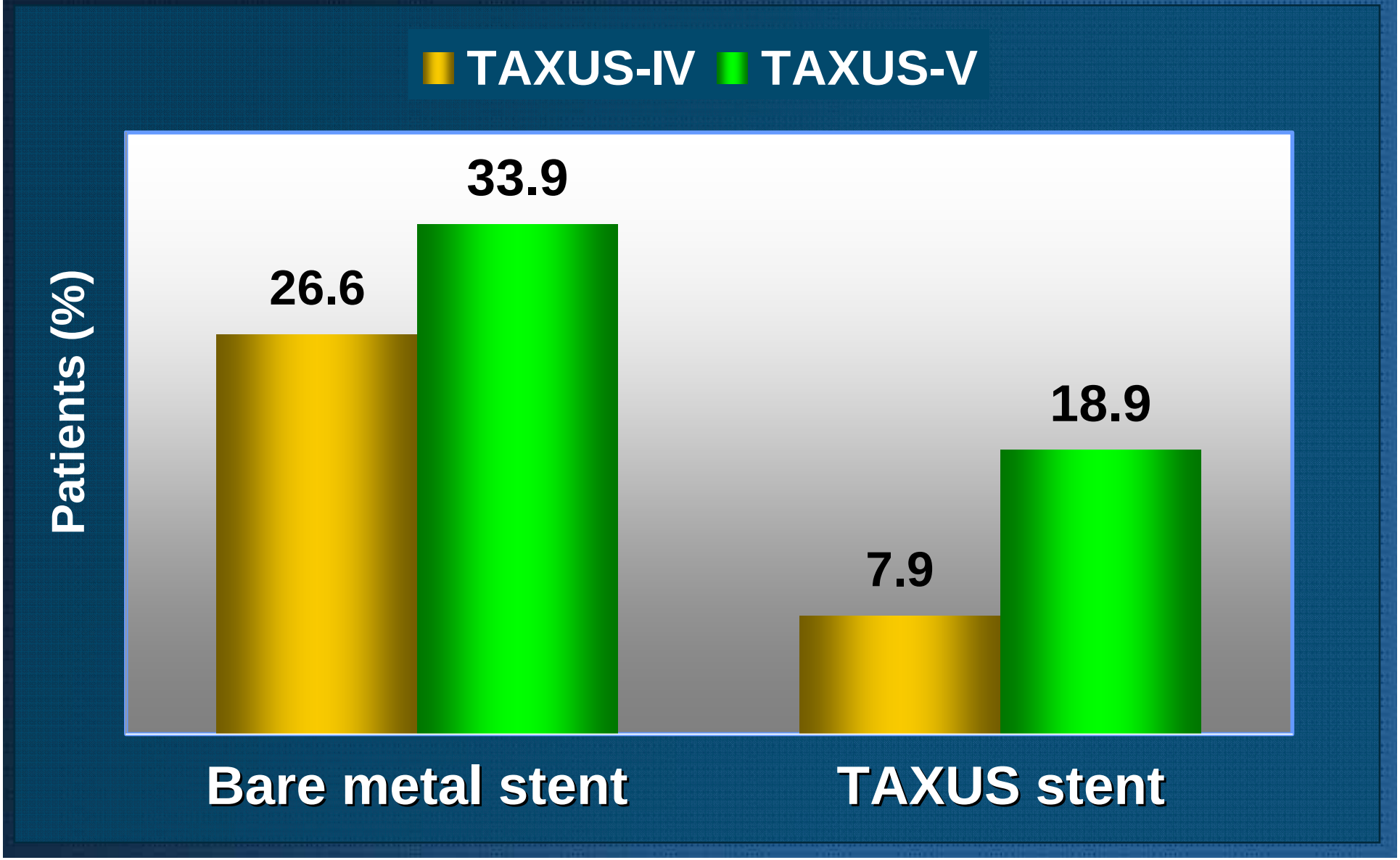
Binary Restenosis at 9 Months



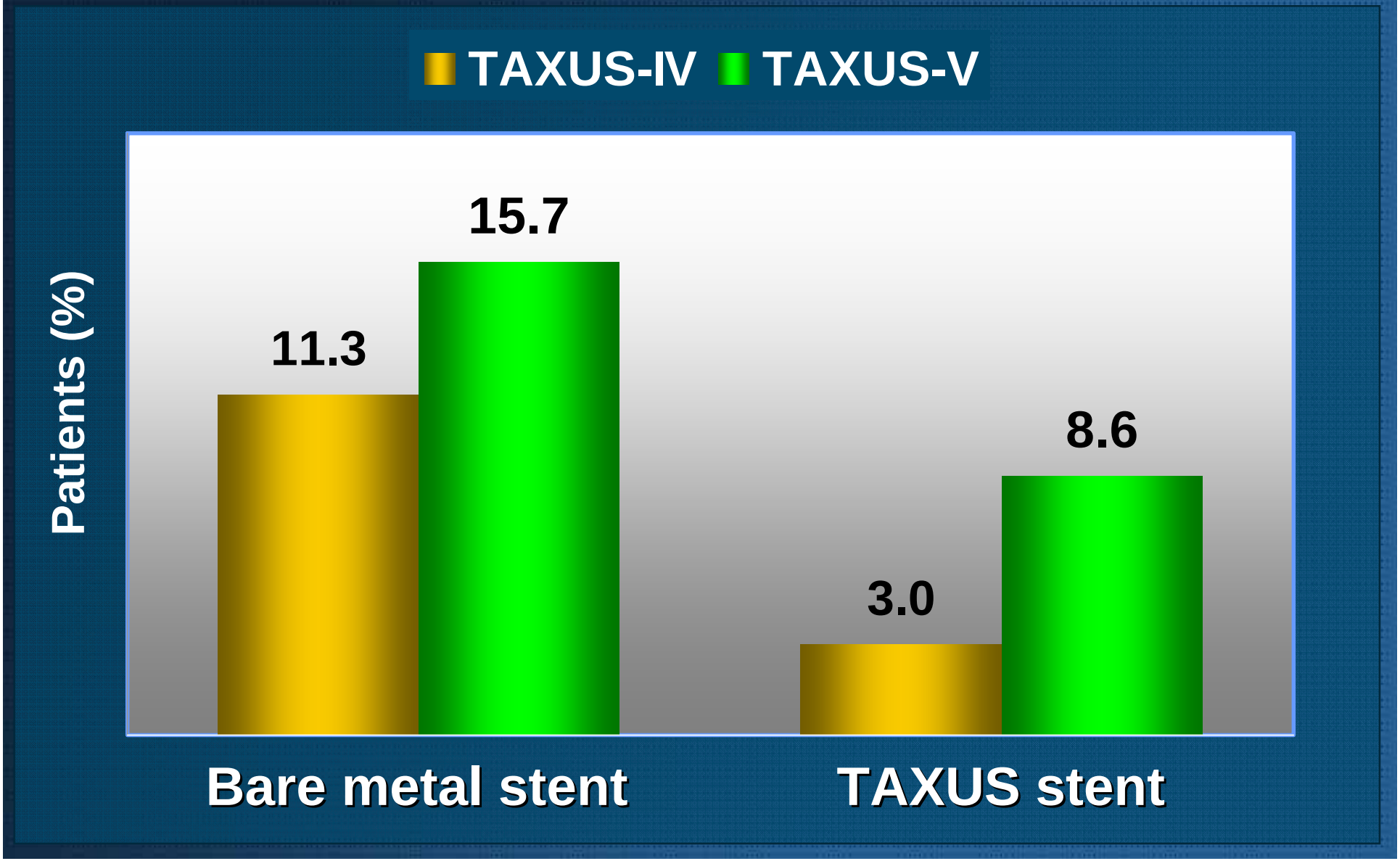
Late loss (in-stent): TAXUS IV and V



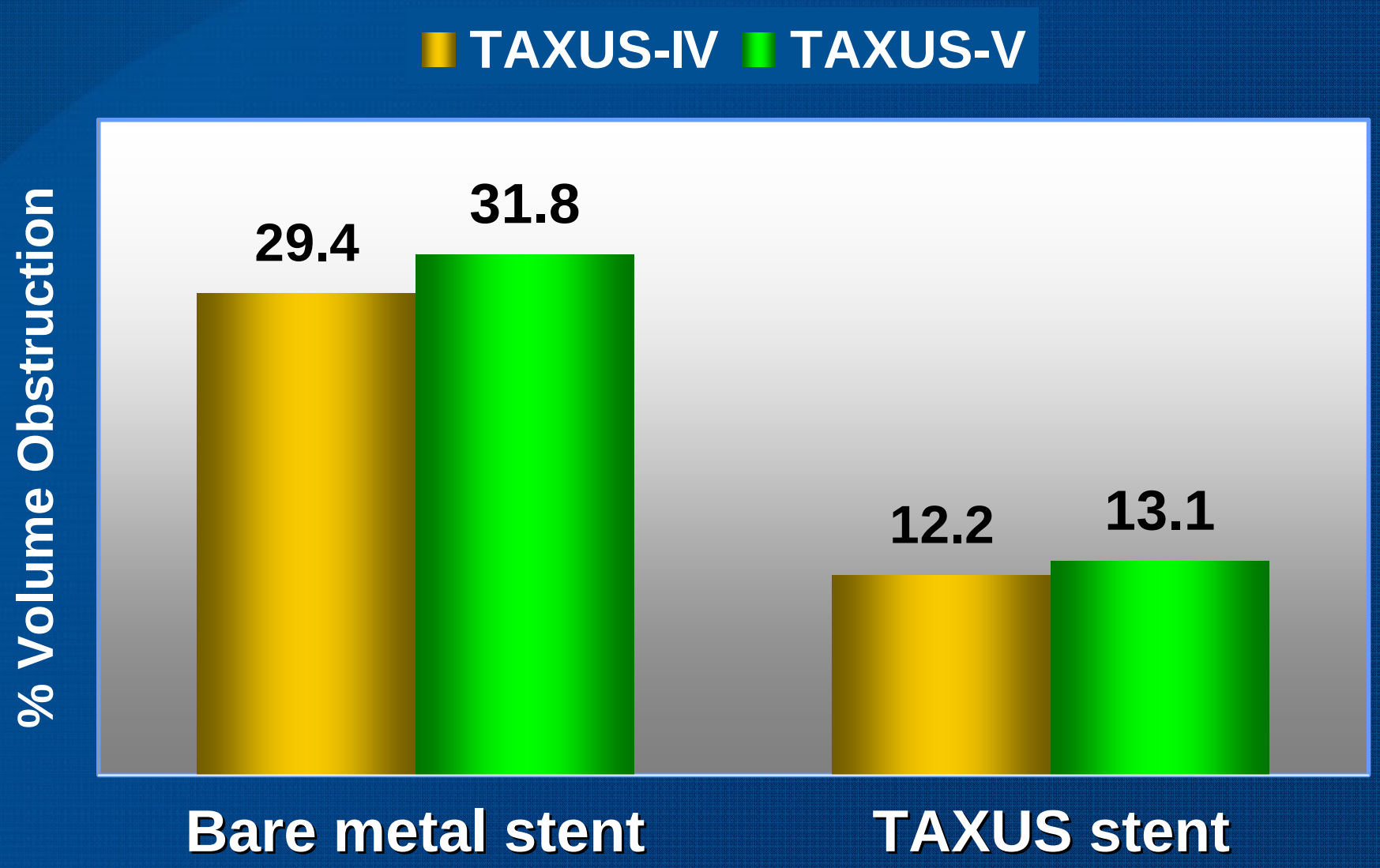
Restenosis (in-segment): TAXUS IV and V



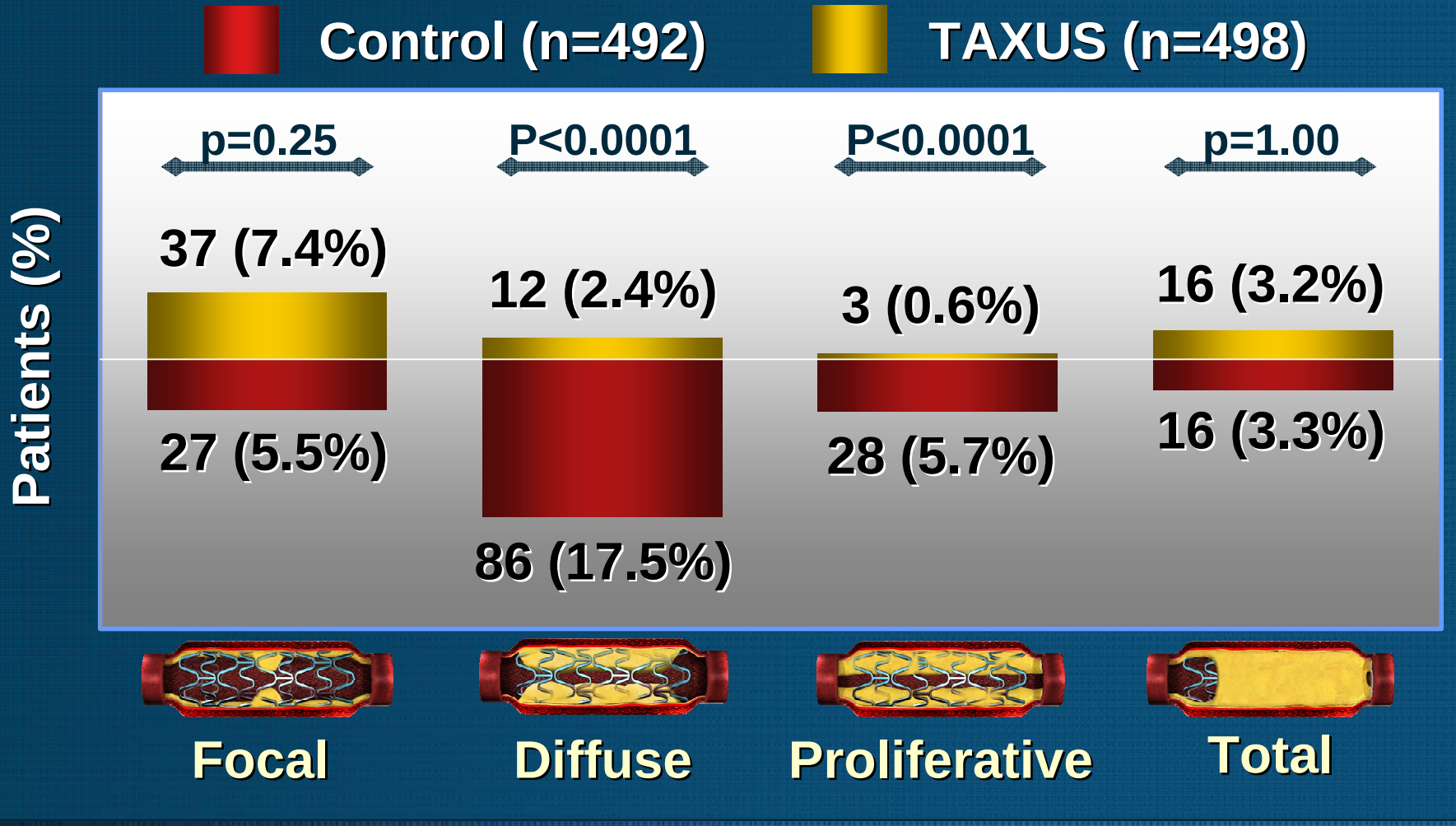
9 Month TLR: TAXUS IV and V



IVUS (%Vol Obstr): TAXUS IV and V

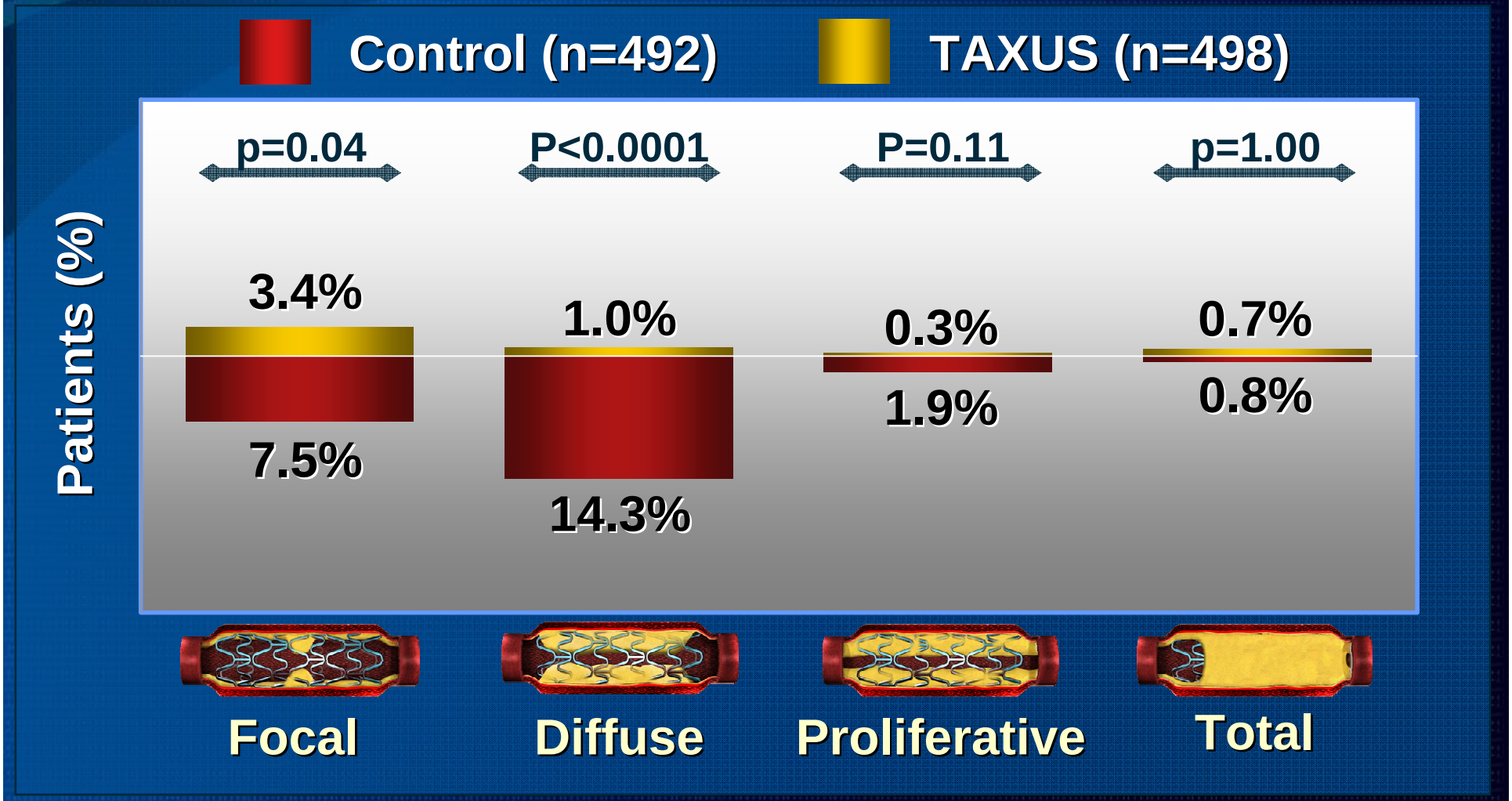


In-Stent Restenosis Pattern



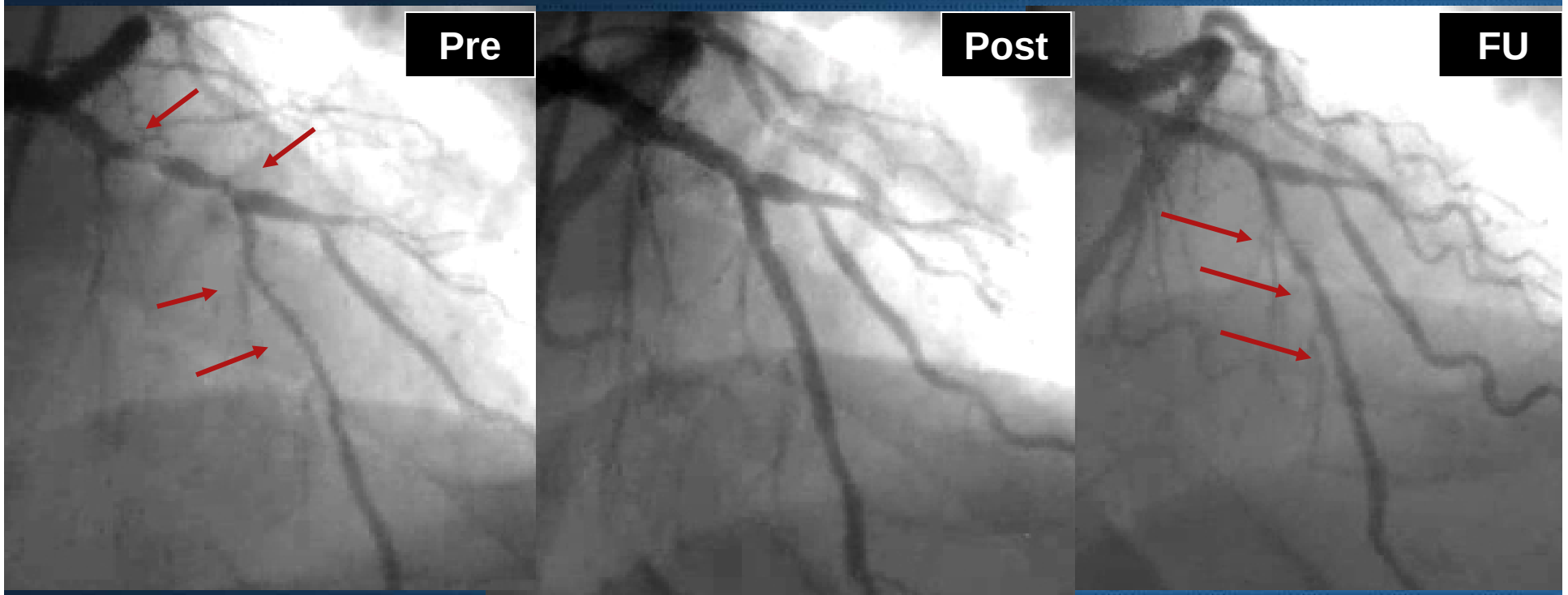
ISR length: 17.9 ± 8.7 mm Control
11.0 ± 6.2 mm TAXUS
p<0.0001

In-Stent Restenosis Pattern



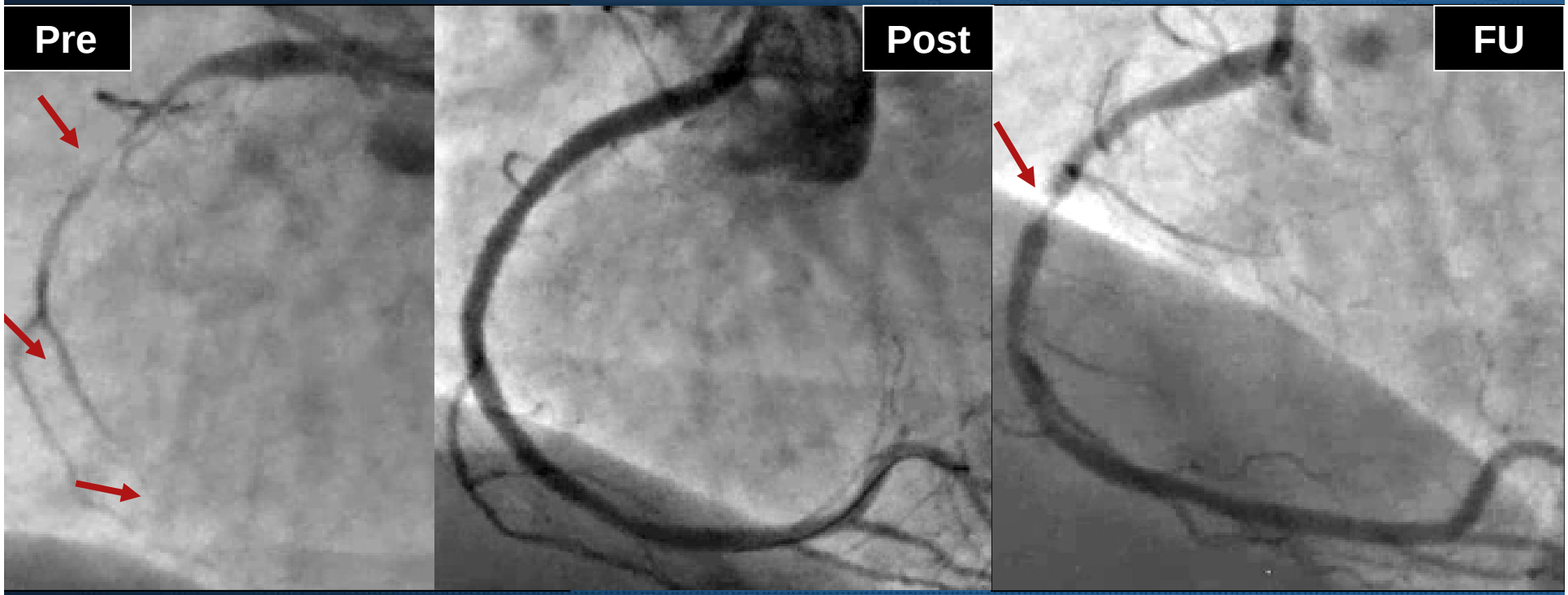
ISR length: 15.3 ± 8.2 mm Control
9.8 ± 5.8 mm TAXUS
p<0.0001

Express Stent Restenosis



Lesion length: 48.7 mm
3 Control stents (16, 24,16 mm)

TAXUS Stent Restenosis



Lesion length = 54.2 mm
2 TAXUS stents, 32 and 32 mm

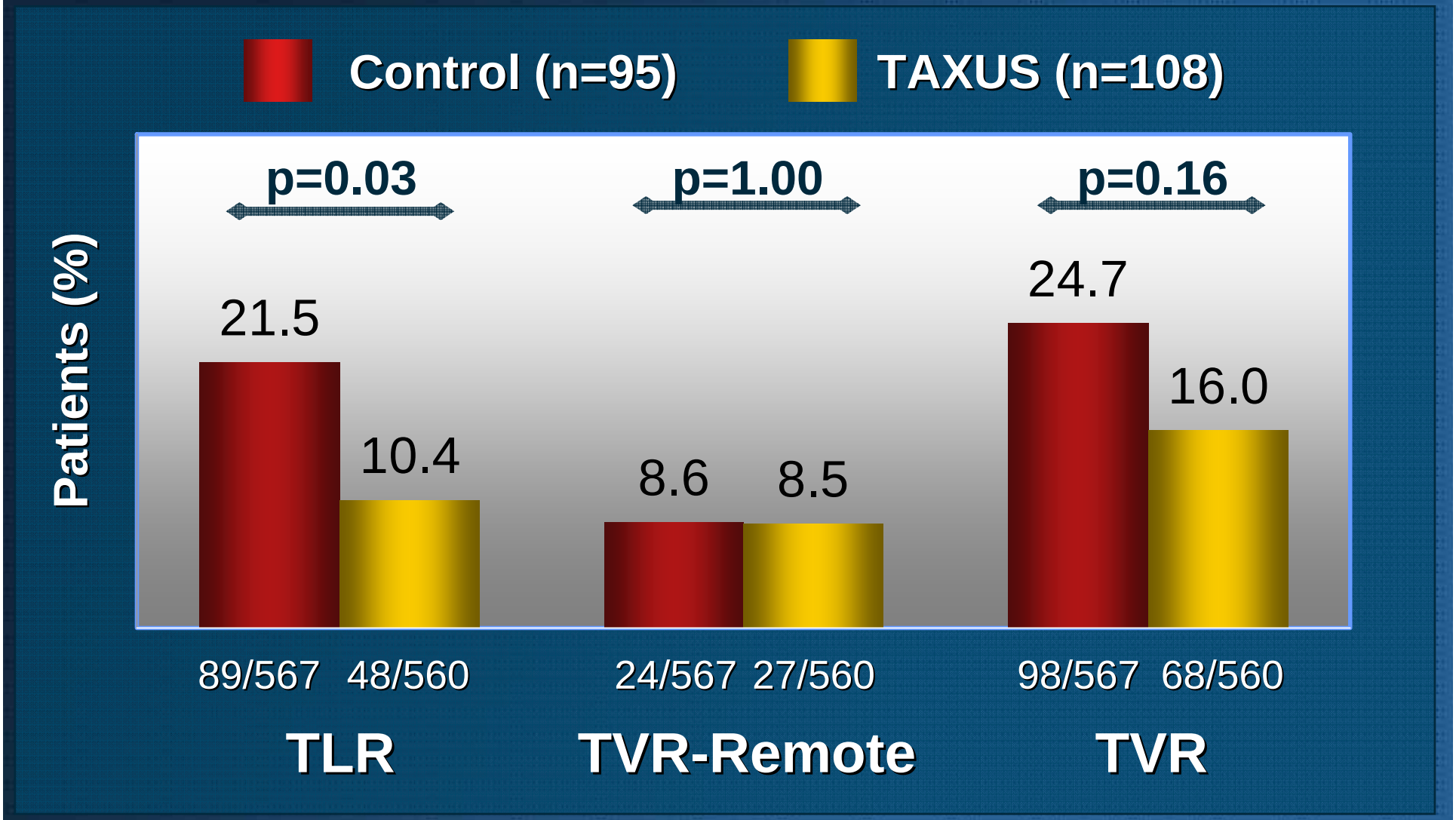
Baseline Characteristics

2.25 mm Stent Subgroup (n=203)

	Control n=95	TAXUS n=108	P value
Diabetes	31.6	47.2	0.03
RVD (mm)	2.10 ± 0.33	2.07 ± 0.31	0.40
Lesion length (mm)	16.4 ± 9.2	16.4 ± 9.6	1.00
Stent length (mm)	26.8 ± 12.4	26.4 ± 12.1	0.83
Multiple stents %	35.8	34.3	0.88

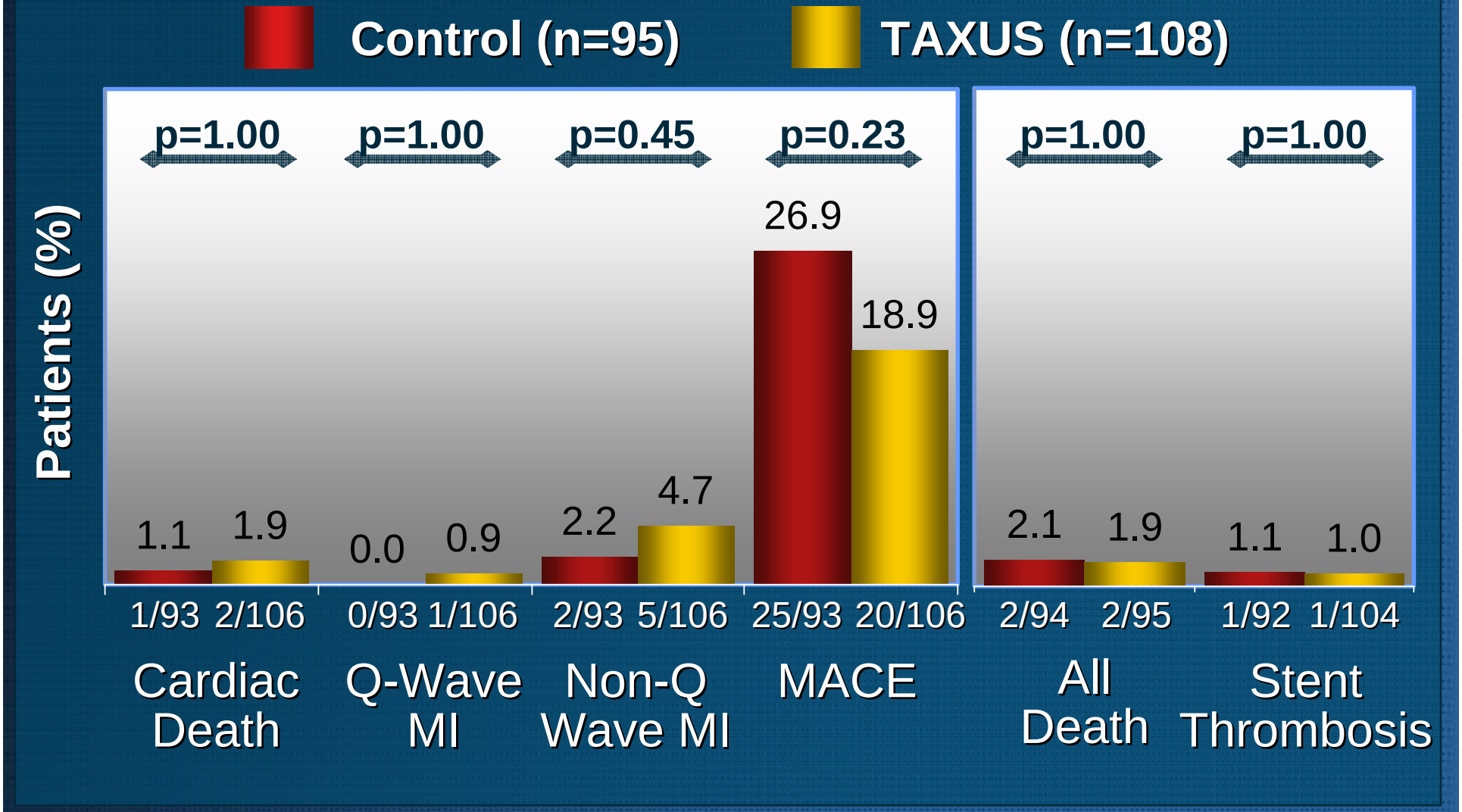
9-Month TLR and TVR

2.25 mm Stent Subgroup (n=203)



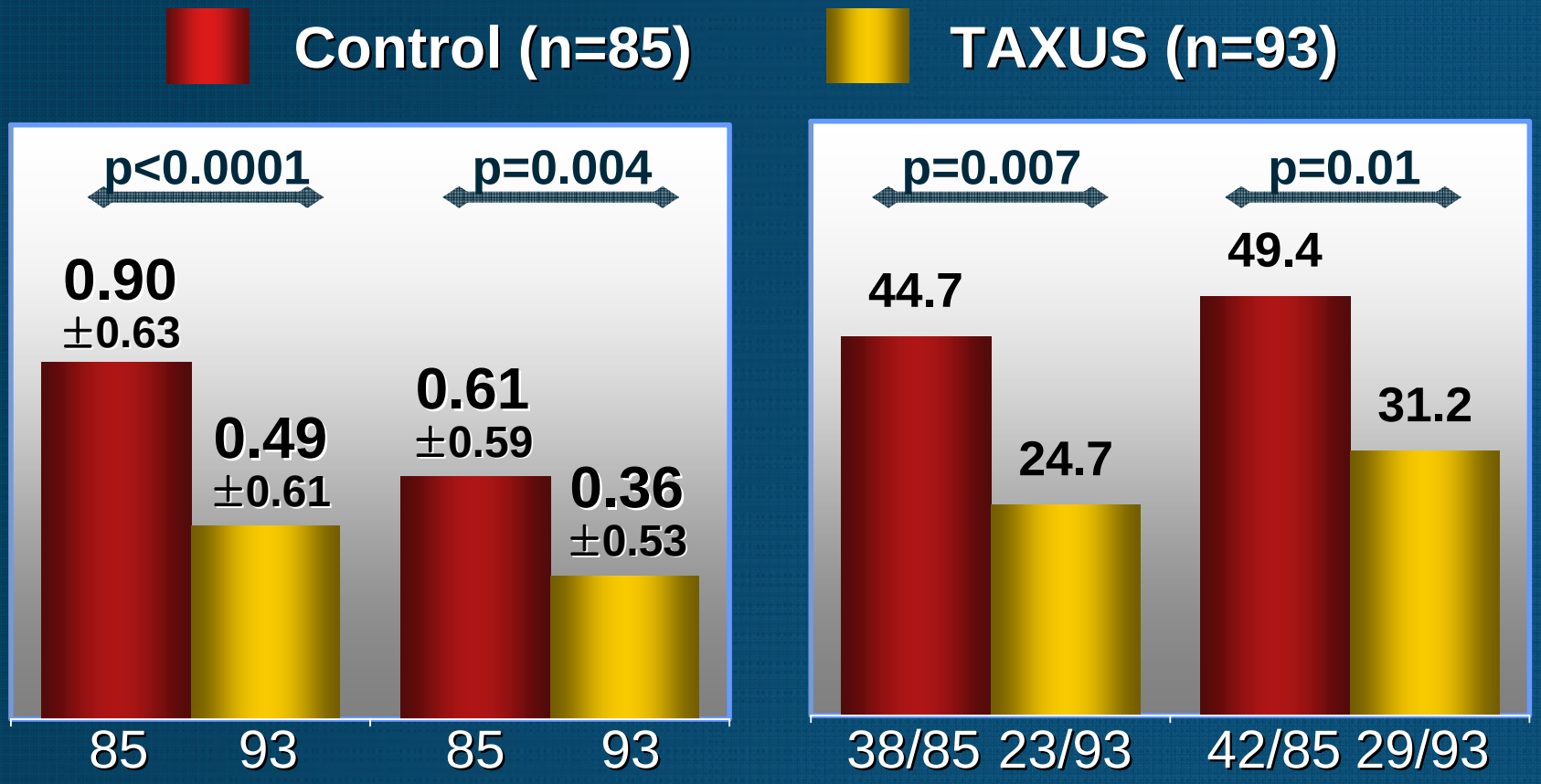
9-Month Safety Summary

2.25mm Stent Subgroup (n=203)



9-Month Angiography

2.25 mm Stent Subgroup (n=203)



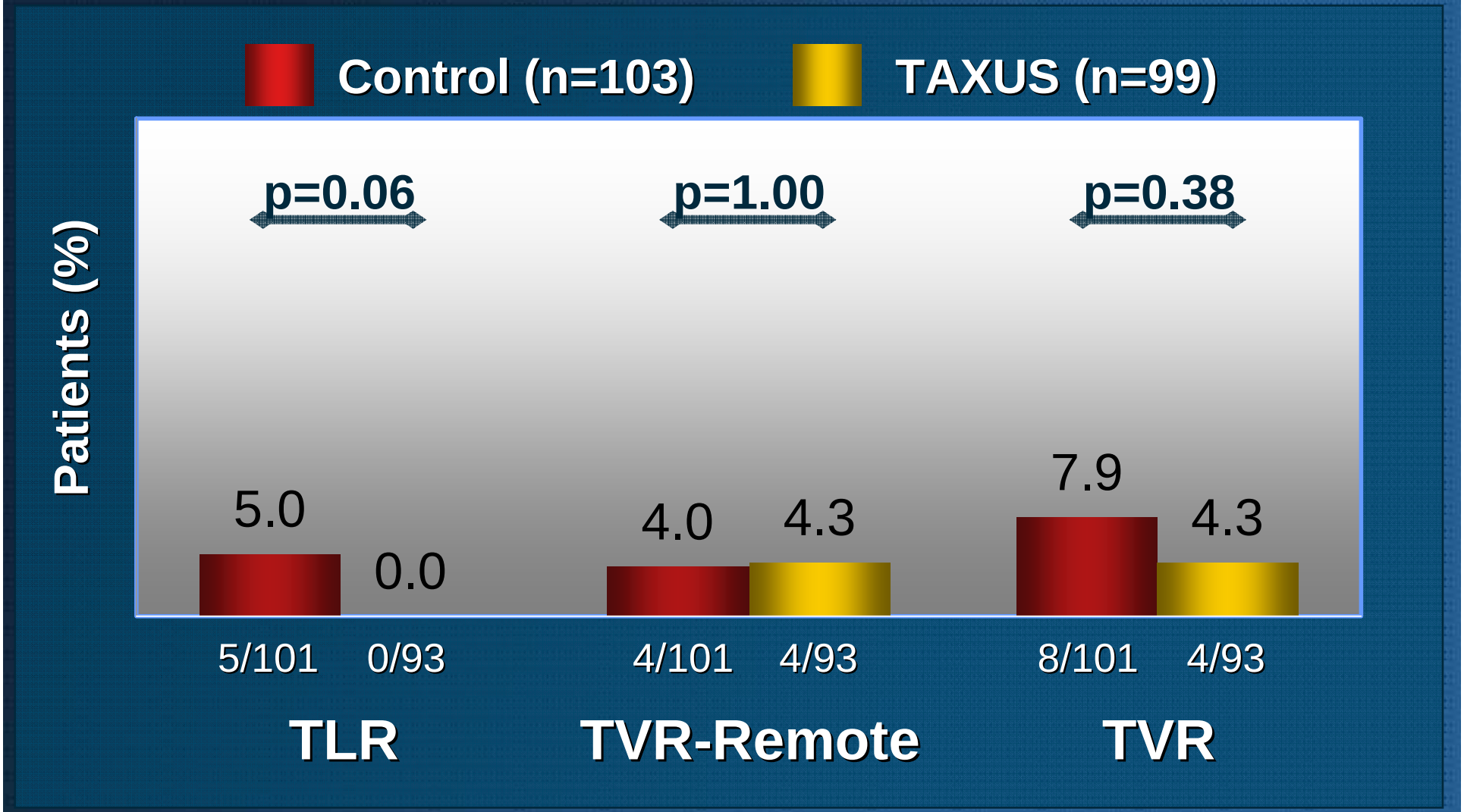
Baseline Characteristics

4.0 mm Stent Subgroup (n=202)

	Control n=103	TAXUS n=99	P value
Diabetes	22.3	29.3	0.27
RVD (mm)	3.33 ± 0.44	3.41 ± 0.45	0.19
Lesion length (mm)	16.0 ± 8.0	16.5 ± 8.5	0.68
Stent length (mm)	26.8 ± 11.9	25.8 ± 11.6	0.55
Multiple stents %	25.2	23.2	0.75

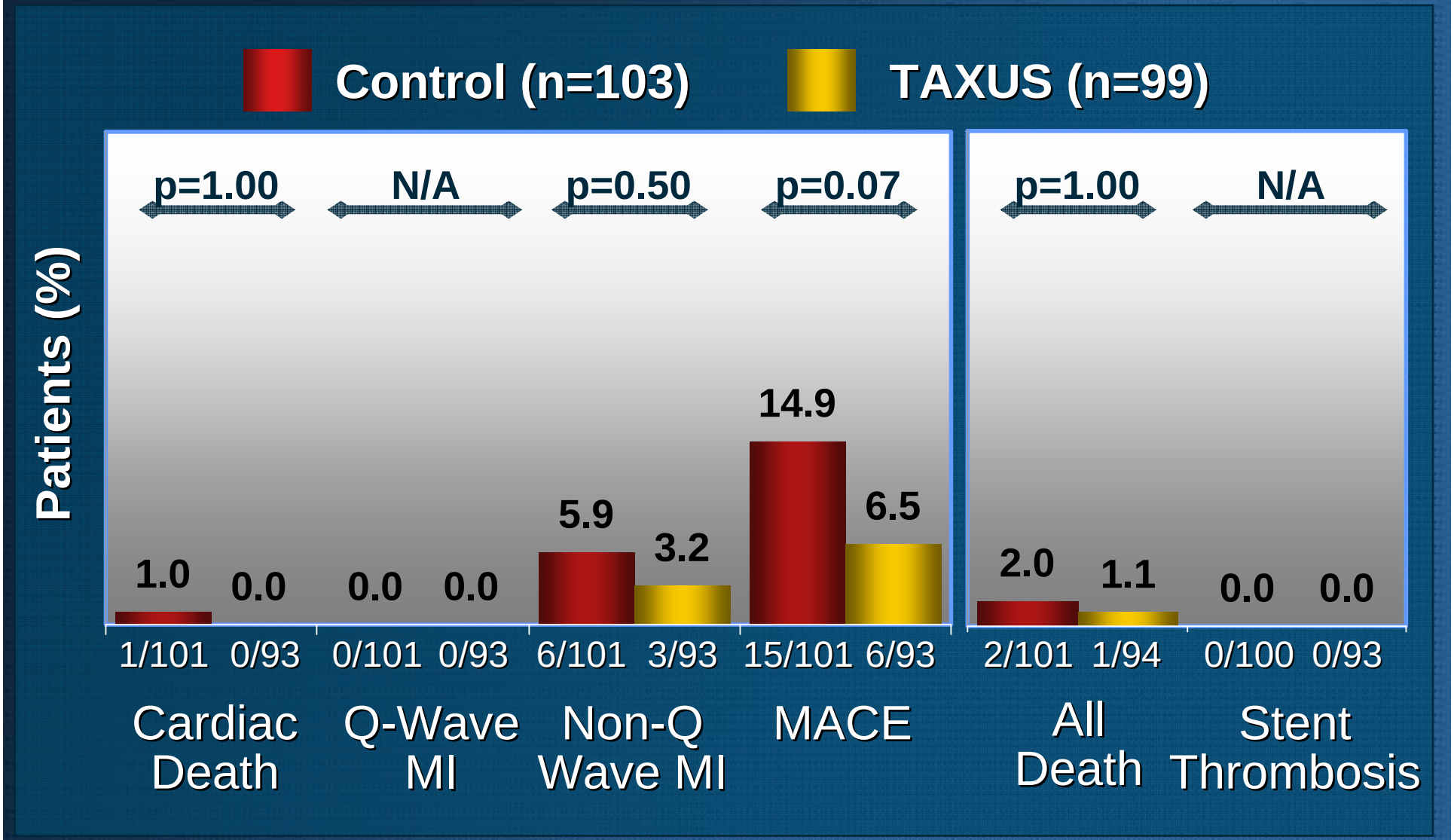
9-Month TLR and TVR

4.00 mm Stent Subgroup (n=202)



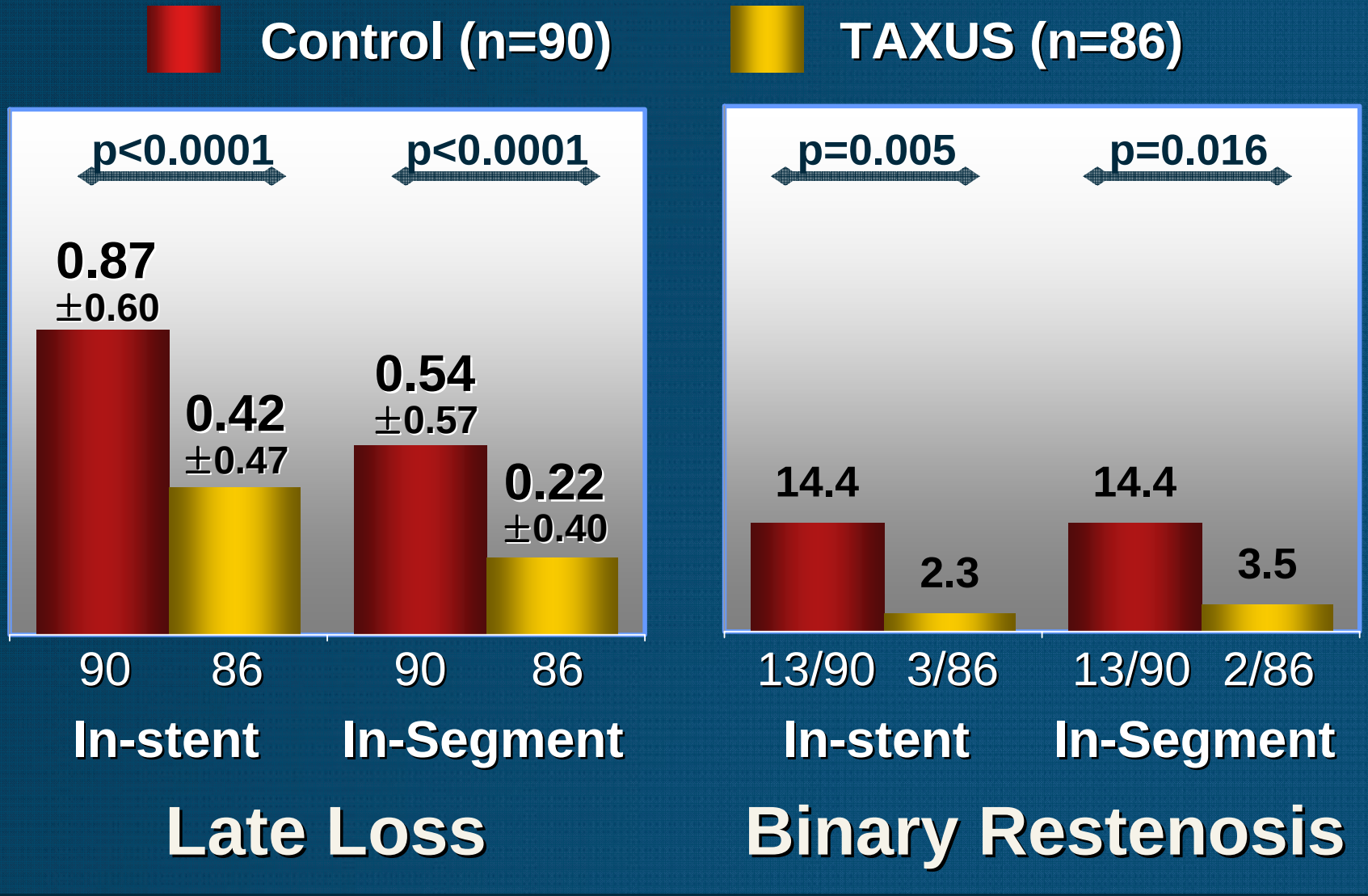
9-Month Safety Summary

4.00 mm Stent Subgroup (n=202)

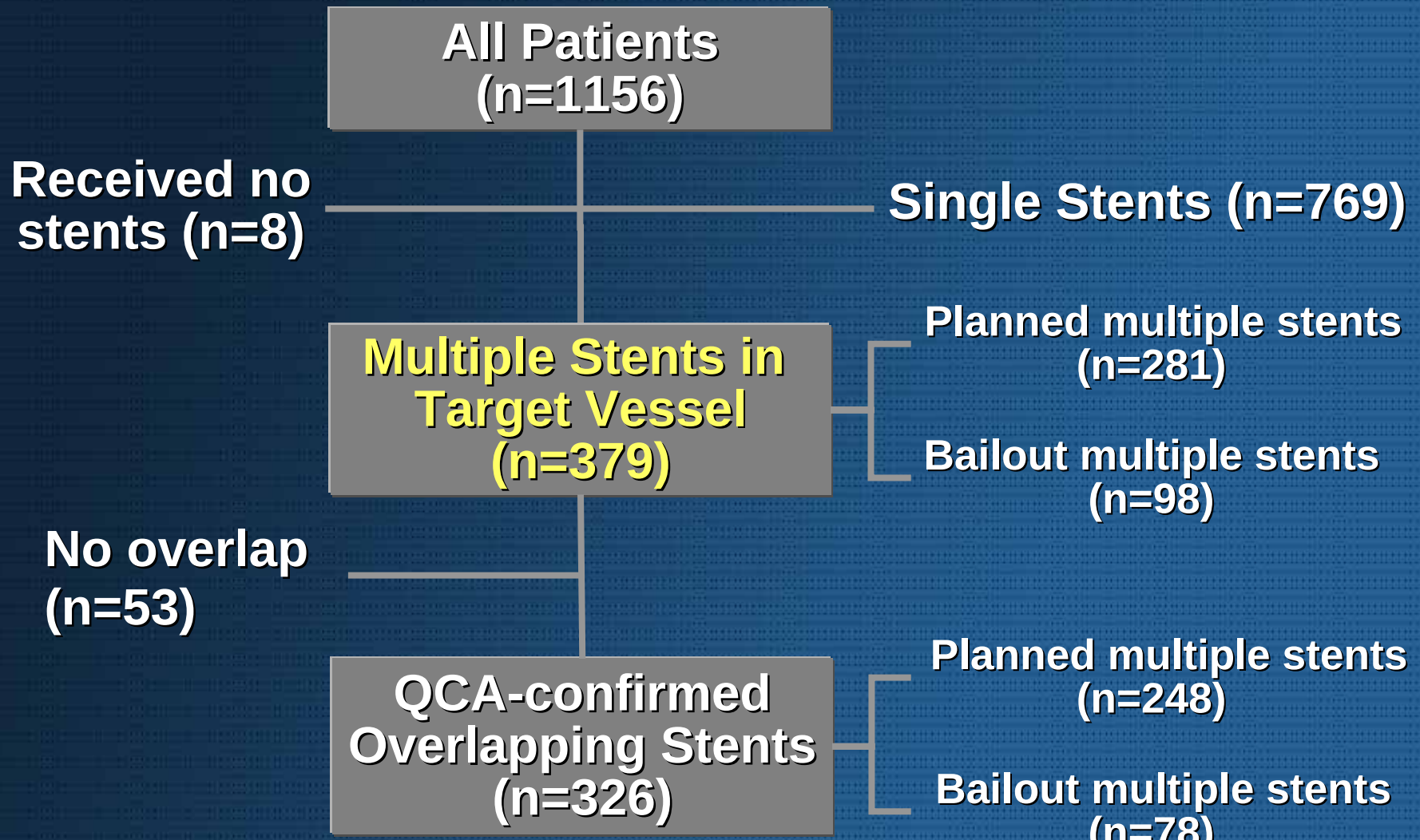


9-Month Angiography

4.00 mm Stent Subgroup (n=202)



Multiple Overlap Stents in TAXUS V



Baseline Characteristics
Multiple Stent Subgroup (n=379)

	Control n=184	TAXUS n=195	P value
Diabetes	33.7	34.9	0.83
RVD (mm)	2.68±0.56	2.65 ±0.55	0.63
Lesion length (mm)	25.7±10.4	25.0 ±9.6	0.50
Stent length (mm)	43.8±10.4	43.6±10.5	0.84
Type C lesions (%)	75.0	72.3	0.64

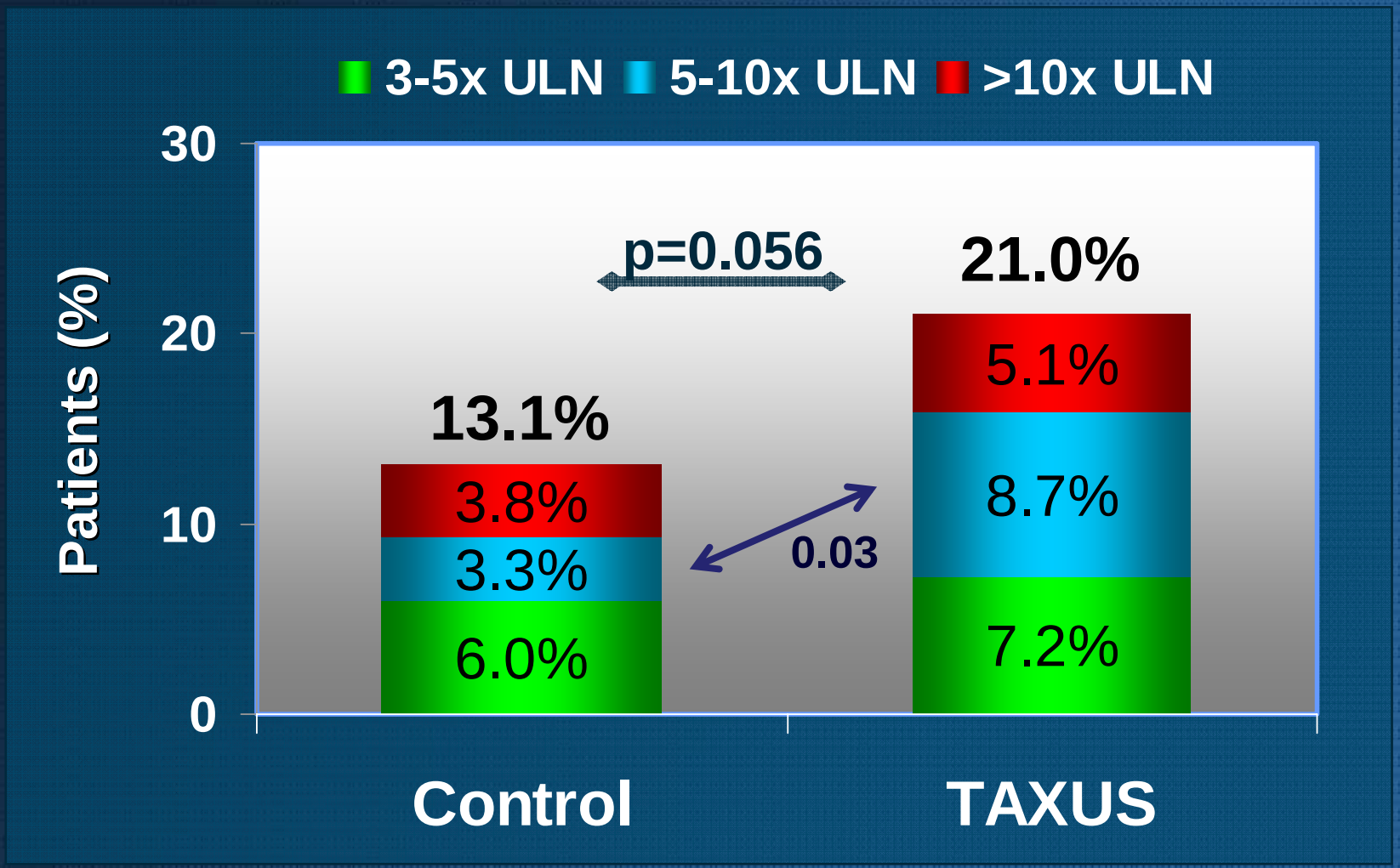
30 Day MACE

Multiple Stent Subgroup (n=379)

	Control n=184	TAXUS n=195	P value
MACE, Overall (%)	3.3	8.3	0.047
Cardiac Death	0.0	0.0	-
MI	3.3	8.3	0.047
Q-wave	0.0	1.0	0.50
Non Q-wave	3.3	7.3	0.11
TVR	0.5	1.6	0.62
TLR	0.5	1.6	0.62
All death (%)	0.0	0.0	-
Stent thrombosis (%)	0.5	1.0	1.00

30 Day MI Frequency and Magnitude

Multiple stent pts (n=379)

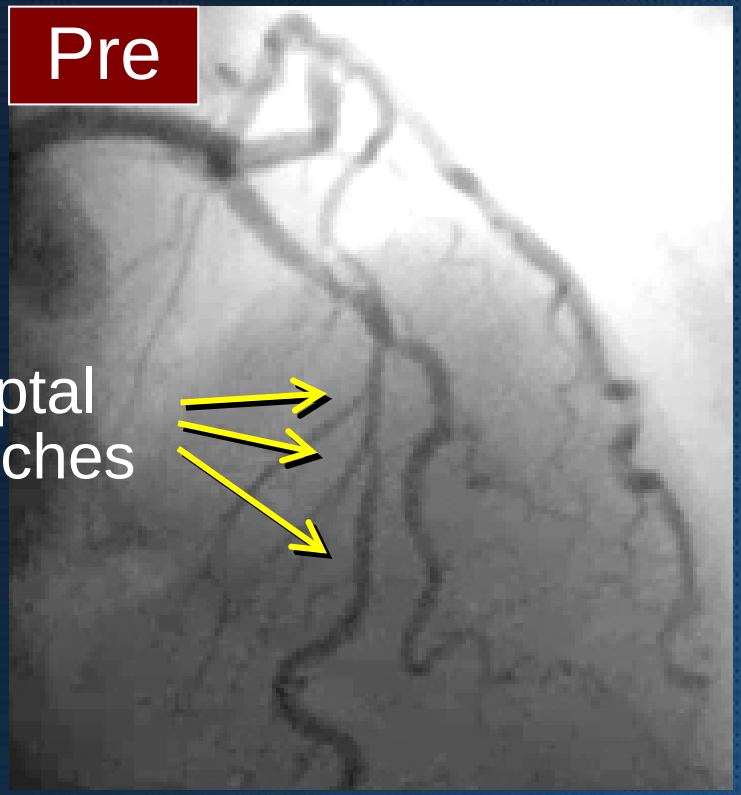


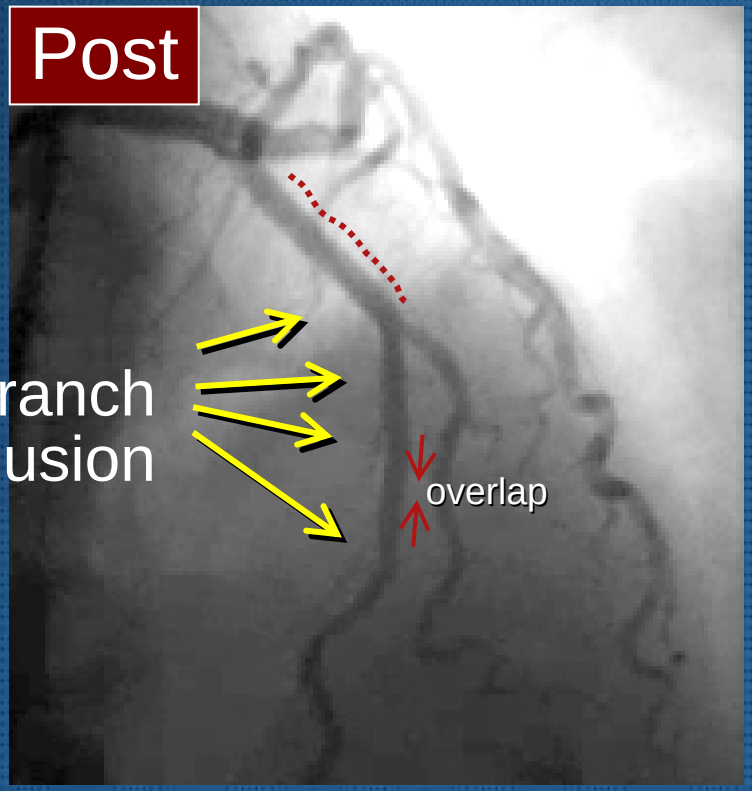
Side Branch Analysis in Multiple Stenting

Core Laboratory Analysis (blinded)

Per Patient	Control n=184	TAXUS n=188	P value
Branch TIMI Flow Reduction (anytime)	28.6 (42/147)	41.9 (65/155)	0.016
Any Side Branch Narrowing (by >70% or to 100%)	30.6 (45/147)	42.6 (66/155)	0.033
Any Side Branch Occlusion	20.4 (30/147)	27.1 (42/155)	0.18

Case 1 – Side branch loss

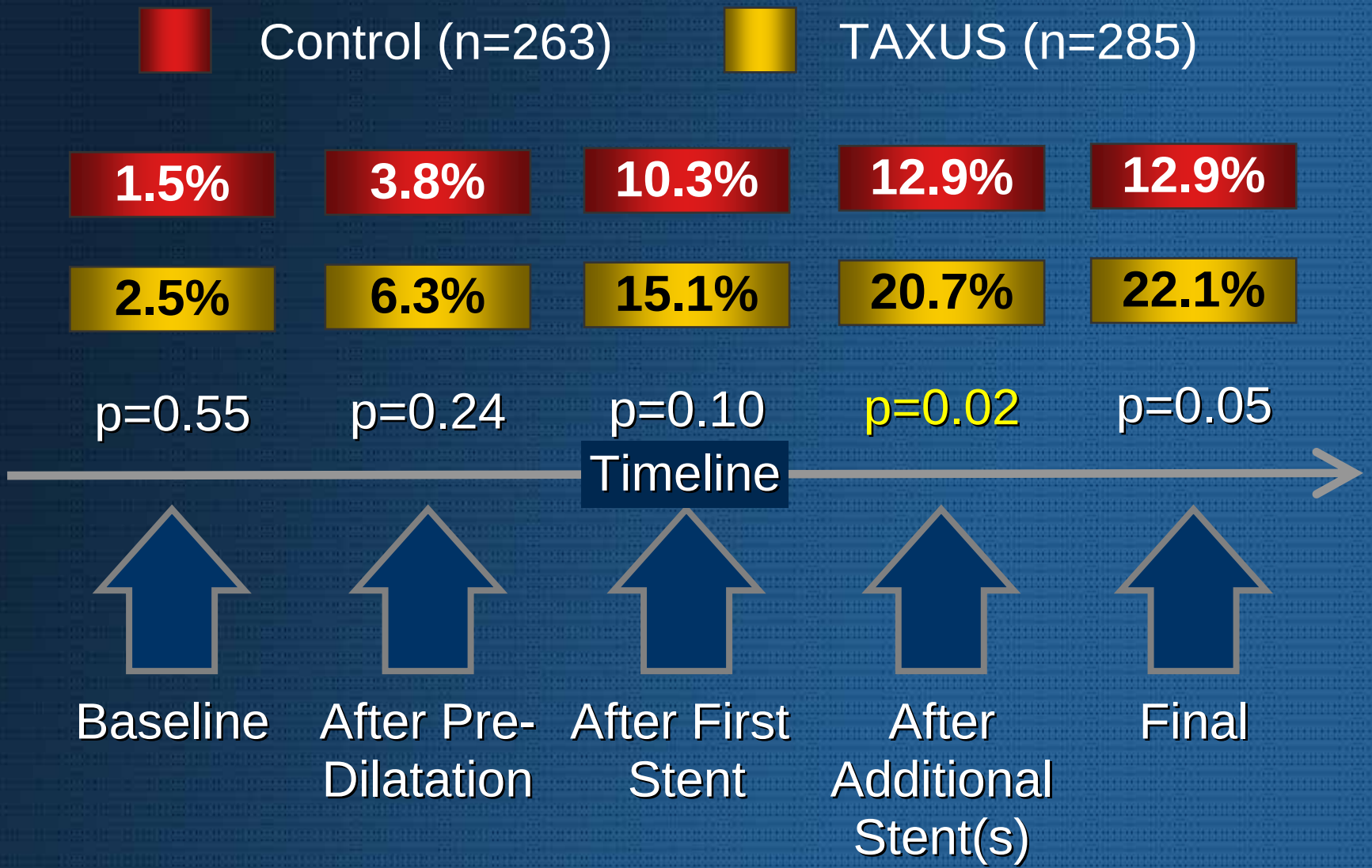




- **Loss of 2 septal branches after implantation of first MLAD stent**
- **Implantation of second MLAD stent to cover distal dissection led to loss of the third septal branch (in non overlap zone)**
- **Implantation of a third stent in PLAD resulted in loss of 4th small septal branch**

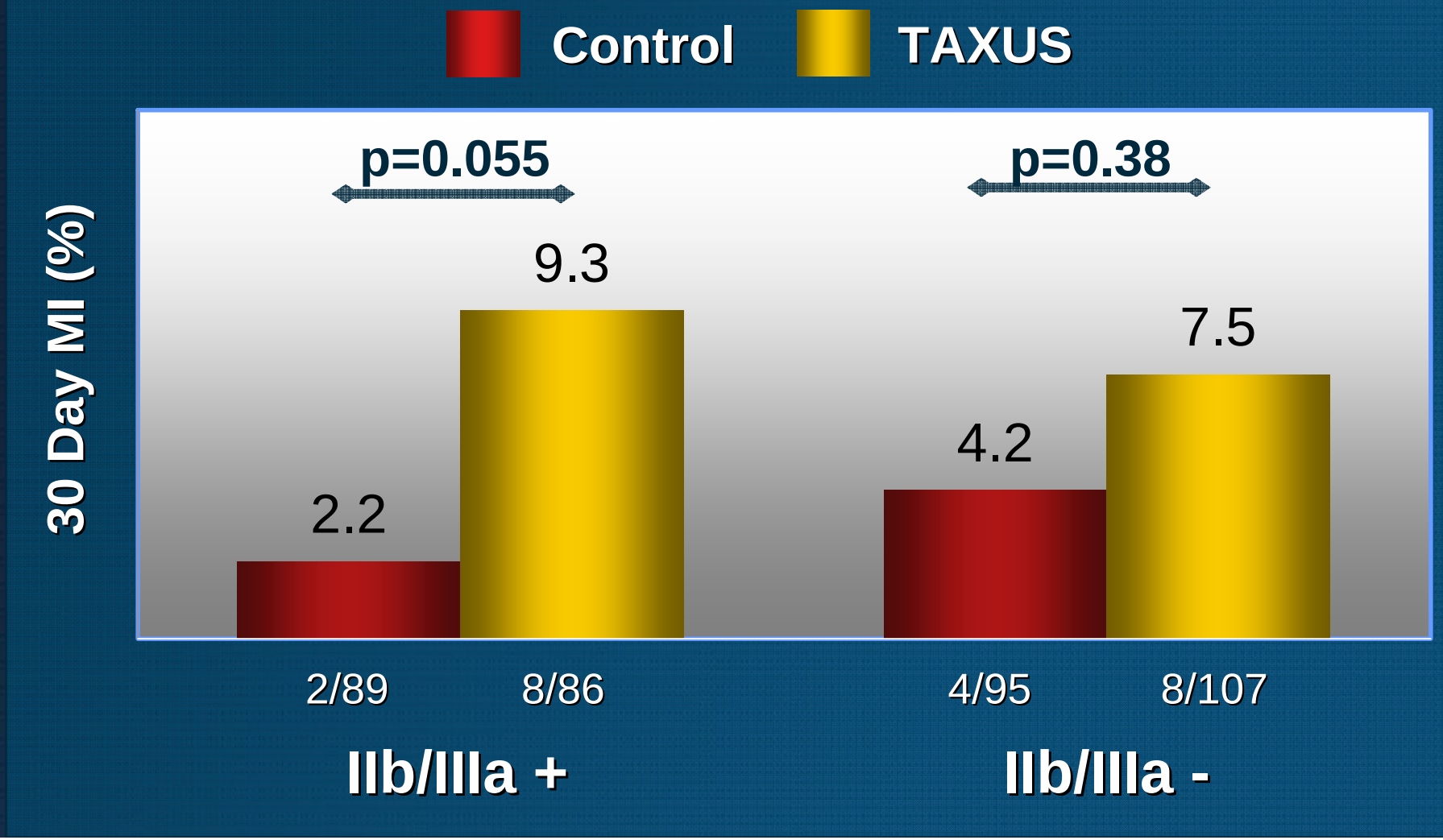
Side Branch Analysis in Multiple Stenting

TIMI Flow ⇓: Timing, Any Time Point



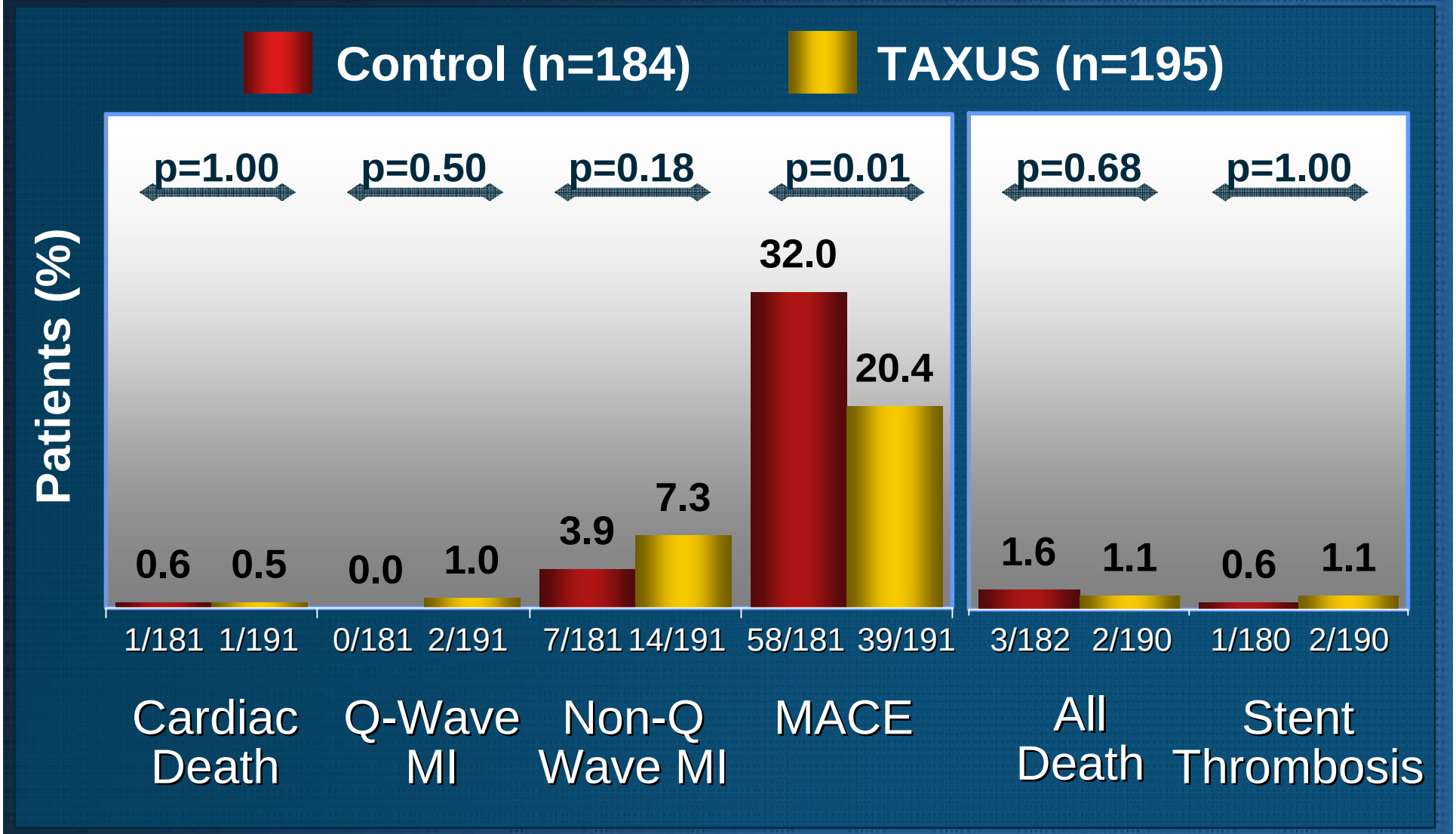
GP IIb/IIIa and Peri-procedural MI

Multiple stent pts (n=379)



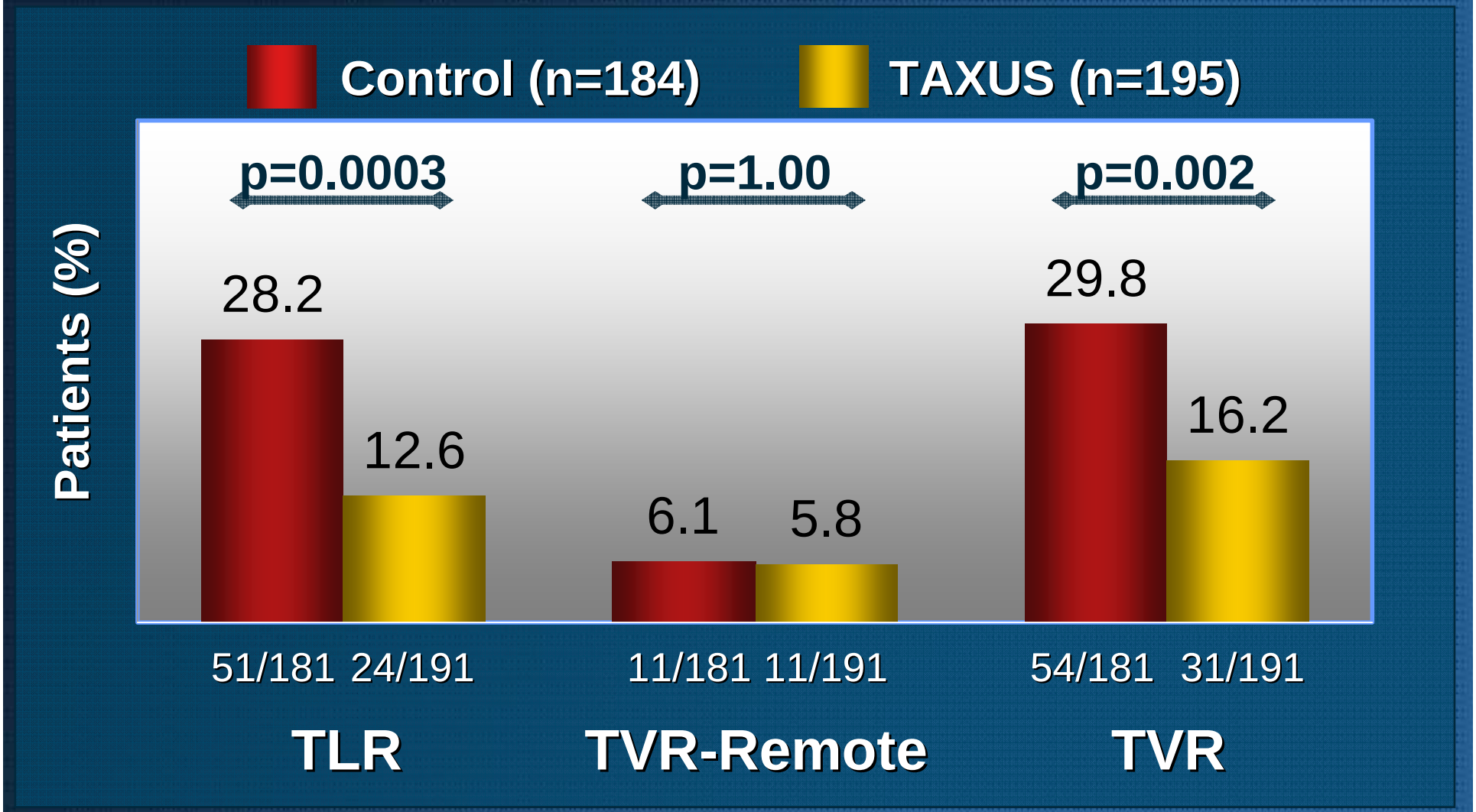
9-Month Safety Summary

Multiple Stent Subgroup (n=379)



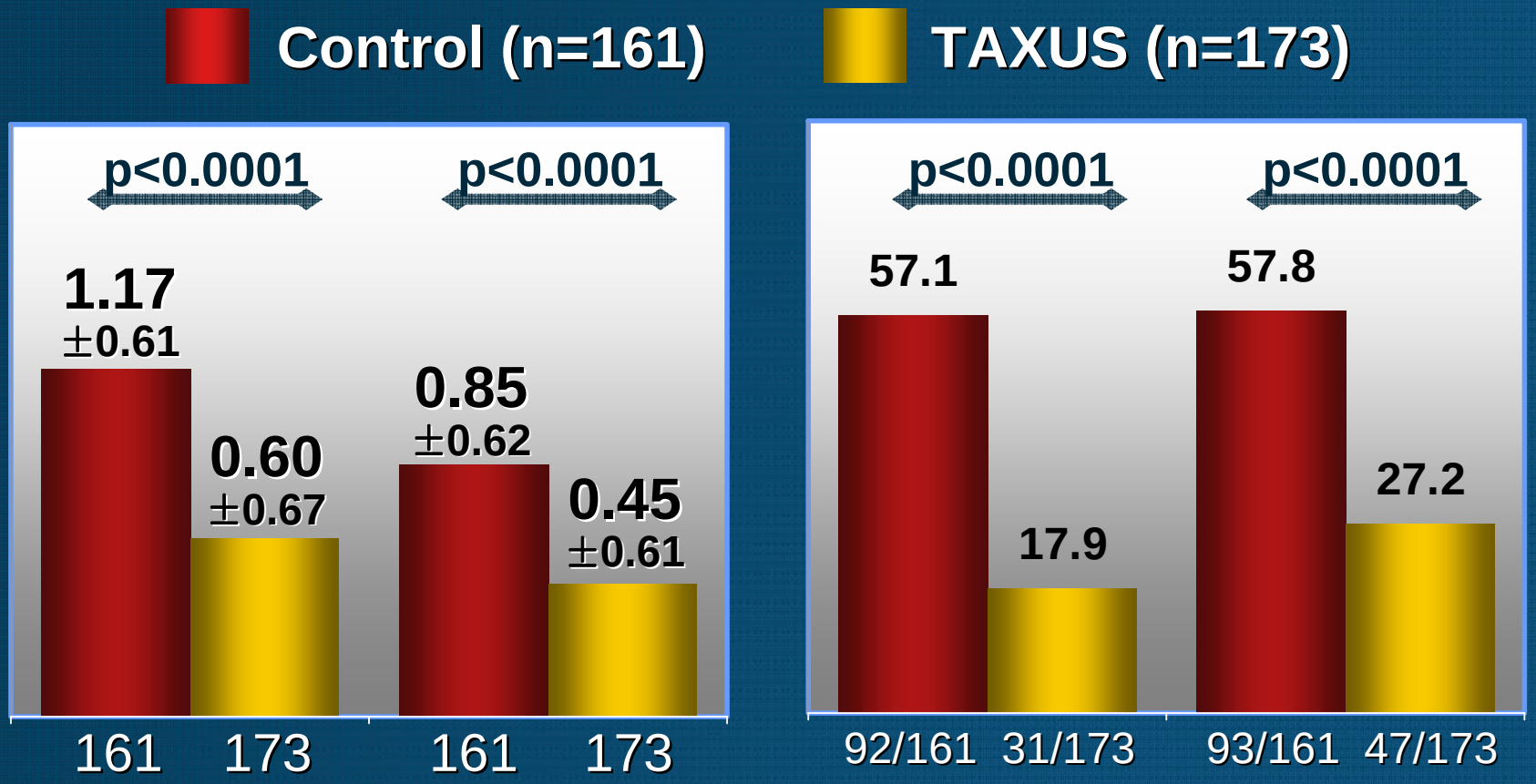
9-Month TLR and TVR

Multiple Stent Subgroup (n=379)



9-Month Angiography

Multiple Stent Subgroup (n=379)



Conclusions I

- **TAXUS V** represents the most complex patient and lesion cohort yet subjected to a blinded, randomized controlled DES trial
- In this complex patient population, the slow-release, polymer-based paclitaxel-eluting TAXUS stent compared to an identical bare metal stent:
  - **Was safe,** wit h overall similar rates of death, MI and stent thrombosis at 30 days and 9 months
  - **Was highly effective,** with marked reductions in clinical and angiographic restenosis, though angiographic late loss and TLR rates were higher than previously noted in less complex lesions

Conclusions II: Subsets

- **The 2.25 mm TAXUS stent ⇒ reduced TLR and restenosis rates**
- **The 4.0 mm TAXUS stent ⇒ marked ⇓ in angiographic restenosis with a strong trend toward reduced TLR**
- **Multiple TAXUS stents ⇒**
  - Statistically significant increase in peri-procedural MACE due to greater myonecrosis from side branch narrowing with decreased flow
  - No differences in death, cardiac death or stent thrombosis
  - Marked ⇓ in clinical and angiographic restenosis